

STUDENT NAME: FAIDA JOY

STUDENT NUMBER: FDXJOY001

DEGREE: LLM (MARINE AND ENVIRONMENTAL
LAW)

DISSERTATION TITLE: BIOSAFETY REGULATION: A COMPARATIVE
ANALYSIS OF THE SOUTH AFRICAN AND UGANDAN EXPERIENCE

SUPERVISOR: ALEXANDER PATERSON

SUBMISSION DATE: 4TH APRIL 2007

Research dissertation presented for the final approval of Senate in fulfillment of part of the requirement for the degree of Master of Laws in approved courses and a minor dissertation. The other part of the requirement for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of Master of Laws dissertation, including relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

Signed by candidate

.....
Signature

Acknowledgements	i
Abstract	ii
LIST OF ACRONYMS	iii
CHAPTER 1	1
CHAPTER 2	5
KEY CONCEPTS	5
2.1 Biosafety, Biotechnology and Genetically Modified Organisms.	5
2.2 The Need for Biosafety Regulation	8
2.3 Adequate Biosafety Regulation	9
CHAPTER 3	11
BIOSAFETY REGULATION UNDER INTERNATIONAL AND REGIONAL INSTRUMENT	11
3.1 Introduction	11
3.2 Convention on Biological Diversity	11
3.3 The Cartagena Protocol on Biosafety	12
3.3.1 Background	12
3.3.2 Objective	13
3.3.3 Scope	14
3.3.4 Advanced Informed Agreement	15
3.4.5 Risk Assessment	17
3.3.6 Risk Management	18
3.3.7 The Precautionary Principle	19
3.3.8 Socio-economic Considerations	20
3.3.9 Public Awareness and Participation	21
3.3.10 Handling, Identification and Packaging	22
3.3.11 Liability, Redress and Compensation	23
3.3.12 Confidential information	24
3.4 The African Model Law on Safety in Biotechnology:	25
3.4.1 Scope	26
3.4.2 Advanced Informed Agreement	26
3.4.3 Precautionary Principle	27
3.4.4 Public Participation	27
3.4.5 Labelling and Identification	28
3.4.6 Liability and Redress	28
3.5 Conclusion	29
CHAPTER 4	31
OVERVIEW OF SOUTH AFRICA'S BIOSAFETY REGIME	31
4.1 Introduction	31
4.2 Principal Legislation	31
4.2.1 The Genetically Modified Organisms Act	31
4.2.2 The GMO Regulations	33
4.2.3 The Genetically Modified Organisms Amendment Bill	33
4.3 The Policy documents	35
4.3.1 Biosafety Policy	35
4.3.2 Guideline Document for use by the Advisory Committee when considering Proposals/Applications for Activities with Genetically Modified Organisms	35

4.3.3 Guideline Documents for Work with Genetically Modified Organisms	36
4.4 Other Relevant Legislation	36
4.4.1 The Constitution of the Republic of South Africa Act	36
4.4.2 Promotion of Access to Information Act	38
4.4.3 Promotion of Administrative Justice Act.....	38
4.4.4 The National Environmental Management Act	39
4.4.5 The Foodstuffs, Cosmetics and Disinfectants Act.....	42
4.4.6 The National Environmental Management Biodiversity Act	42
CHAPTER 5	44
CRITIQUE OF SOUTH AFRICA’S BIOSAFETY REGIME.....	44
5.1 Objectives and Scope of the GMO Act.....	44
5.2 Institutional Arrangements.....	44
5.3 Risk Assessment	46
5.4 Liability Regime	48
5.5 Decision-making	49
5.6 Public Participation.....	50
5.7 Labelling Requirements.....	51
5.8 Confidentiality and Access to Information	53
5.9 Administrative Justice Provisions.....	54
5.10 Appeals	55
5.11 Fast Track Mechanism.....	56
5.12 Enforcement and Compliance mechanisms	56
5.13 Unintentional Release and Emergency Measures.....	57
5.14 Prohibition of Activities.....	58
5.15 Inconsistency with Other Laws.....	58
5.16 Conclusion:	59
CHAPTER 6	60
OVERVIEW OF UGANDA’S BIOSAFETY REGIME.....	60
6.1 Introduction.....	60
6.2 Principal Legislation	60
6.2.1 Draft National Biosafety Regulations.....	60
6.2.2 Uganda Biosafety Bill.....	62
6.3 Relevant Policy	63
6.3.1 The National Biotechnology and Biosafety Policy.....	63
6.3.2 The Guidelines for Biosafety in Biotechnology for Uganda	64
CHAPTER 7	65
CRITIQUE OF UGANDA’S BIOSAFETY REGIME	65
7.1 Scope and Exclusions	65
7.2 Institutional Arrangements.....	66
7.3 Application and Approval Procedures	67
7.4 Decision-making Procedure.....	68
7.5 Review of Decisions	69
7.6 Public Awareness and Participation.....	69
7.7 Risk Assessment and Risk Management	71
7.8 Confidentiality and Access to information	73
7.9 Exemptions and Fast –Track Procedure	74

7.10 Unintentional Release and Emergency Measures	75
7.11 Liability Regime	75
7.12 Labelling and Identification	76
7.13 Offences and Penalties	76
7.14 Compliance and Enforcement	77
7.15 Legal Authority	78
7.16 Conclusion	78
CHAPTER 8	80
COMPARATIVE ANALYSIS OF SOUTH AFRICA AND UGANDA'S BIOSAFETY REGIMES	80
8.1 Introduction	80
8.2 Institutional Arrangement	80
8.3 Decision-making	82
8.4 Public participation	83
8.5 Risk Assessment	83
8.6 Liability and redress	84
8.7 Labelling and Identification	85
8.8 Compliance and Enforcement	85
8.9 Conclusion	86
CHAPTER 9	87
CONCLUSION	87

Acknowledgements

I wish to acknowledge the assistance of all those who contributed in one way or the other towards the achievement of this work. To the Almighty God, You are my Rock, to you be all the Glory. Mum and Dad, may the good Lord richly bless you for the tireless efforts towards giving me the best, I could not ask for more. Tricia, Franco and Pam, I appreciate you people a lot! Auntie Irene, you are the best God-mum in the whole wide world. I thank God for that big heart. To all my friends both new and old, thank you for being you, encouraging and supportive friends. Last but important, my supervisor Sandy Paterson. Thank you for all the support, encouragement and guidance which I greatly appreciate.

Abstract

This study provides a critical and comparative analysis of biosafety regulation in South Africa and Uganda. The overall objective of the study is to establish which country prescribes a more adequate regulatory regime. Biosafety regulation under international and regional law is the first key aspect that this paper examines. This is done in order to set out a context under which domestic biosafety regulation is examined. This study argues that international law generally sets minimum standards while regional law sets higher standards for biosafety regulation. The second key area examined is biosafety regulation in South Africa. The paper sets out an overview of the relevant biosafety laws in South Africa and conducts a critical analysis of these laws pointing out their strengths and weaknesses. The study is premised on the argument that South African regulatory regime is inadequate for purposes of regulating biosafety.

The third part of this paper focuses on Uganda's regulatory regime. A similar analysis was carried where the study found that the Ugandan regime is reasonably adequate for purposes of protection of the environment and human health. The final key aspect of this paper is a comparative analysis of biosafety regulation in South Africa and Uganda. This is done thematically, setting out differences and similarities. This part examines the extent to which South Africa and Uganda have attempted to comply with their international obligations. This paper concludes that, although the Ugandan regulatory regime (both existing and proposed) has some weaknesses, it is a more adequate regime than the South African one. Further, Uganda is more compliant with the biosafety Protocol and the African Model Law than South Africa.

List of Acronyms

AIA	Advanced Informed Agreement
AU	African Union
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
COP	Conference of the Parties
EIA	Environmental Impact Assessment
EU	European Union
FAO	Food and Agricultural Organization
FCDA	Foodstuffs, Cosmetics and Disinfectants
FFP	Food, Feed and Processing
GATT	General Agreements on Tariffs and Trade
GE	Genetic Engineering
GM	Genetic Modification
GMO	Genetically Modified Organisms
IBC	Institutional Biosafety Committee
IPPC	International Plant Protection Convention
LMO	Living Modified Organisms
NBC	National Biosafety Committee
NCA	National Competent Authority
NEMA	National Environmental Management Act
OAU	Organization of African Union
PAIA	Promotion of Access to Information Act
PAJA	Promotion of Access to Justice Act
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
UNCST	Uganda National Council for Science and Technology
UNEP	United Nations Environmental Programme.
WHO	World Health Organization.
WTO	World Trade Organization.

CHAPTER 1

INTRODUCTION TO THE STUDY

A key role that governments have to play is to protect the environment and its people from the potential harm associated with GMOs. Yet, Africa is experiencing mounting controversy concerning the role and regulation of modern biotechnology in the continent's economic transformation and sustainable development.¹ According to a 'living paper' prepared for the African Policy Dialogues on Biotechnology, there are four main issues which are subject to intense disagreement and which require to be resolved on the African continent in relation to the regulation of modern biotechnology.² These are the precautionary principle, socio-economic considerations, liability and redress, and public awareness. In addition, issues of labeling and traceability constitute part of the global controversy relating to genetically modified organisms.³ The foregoing are among the critical issues which need to be considered when evaluating biosafety regulation.

The need to regulate genetically modified organisms (GMOs) arose as a response to the development of the recombinant DNA technology in the 1970s.⁴ The global community has not entirely embraced this new form of biotechnology. While the use of this technology in pharmaceuticals and vaccines has been widely accepted, the contrary applies in respect to genetically modified (GM) crops and GM foods.⁵ This attitude reflects a range of concerns associated with GMOs including environmental, health risks and socio-economic impacts.⁶

¹ Governing Biotechnology in Africa: 'Towards Consensus on key Issues in Biosafety', 20-24th September 2004 available at <http://www.ifpri.org/africadialogue/pdf/biosafetypaper.pdf>.

² Ibid.

³ David M and Gavin G, 'Genetically Modified Food Labeling and the WTO Agreements' (2004) 13 (3) *RECEIL* 306 at 306 (specifically referring to the EU and US).

⁴ Governing Biotechnology in Africa, *supra* note 1.

⁵ David et al, *supra* note 3, at 306-307.

⁶ Ibid at 307.

South Africa not only grows GMOs commercially on a large scale, it also imports GM crops.⁷ The common GM crops are GM cotton, soya and maize. South Africa imports GM maize from Argentina and the United States.⁸ Significantly, the country has taken steps to regulate biosafety, through the enactment of the Genetically Modified Organisms Act, (15 of 1997). It is the first country in Africa to enact a specific legislation regulating GMOs

South Africa is arguably the most ‘advanced’ country in Africa in the area of GMOs. It appears to be the trendsetter in this area. However, the precedent South Africa has set faces criticism from skeptics by reason of the inherent weaknesses of its regulatory regime. The regulatory regime lacks in material respects including those pertaining to the precautionary principle, risk assessment and public participation.

Uganda is one of the African states that is trying to put in place specific legislation for biosafety. Although it has not yet enacted an Act for biosafety, quite remarkably Uganda has made substantial efforts towards achieving that goal. Currently a Biosafety Bill 2005 has been drafted. Whether the said Bill sees the light of the day remains to be seen. There are Draft Regulations on Biosafety and other relevant publications including guidelines and policies. The position of the Ugandan Government on GM foods, according to top officials from the National Agricultural Research Organization (NARO), is that ‘GM foods can be considered safe for human consumption until proved otherwise’⁹ thereby adopting the American approach. Interestingly this position is contrary to the precautionary principle.¹⁰ This principle provides that where there are threats of serious or irreversible damage, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.¹¹ As a result, application of the precautionary principle requires that GM foods be presumed unsafe until proved otherwise.

⁷ Mayet M, ‘Why we need to label GMO food’ available at http://www.biosafetyafrica.net/_DOCS/ACB_GEFoodLabelingFactSheet.pdf.

⁸ Ibid.

⁹ <http://www.africabiotech.com/news2/article.php?uid=115>.

¹⁰ The precautionary principle is discussed in detail in part 3.2.7 of this paper.

¹¹ Principle 15, *Rio Declaration on Environment and Development* 31 *I.L.M.* 874, 879

Uganda imports GM foods for consumption but not for cultivation.¹² The government has the support of both scientists and farmers who await the enactment of the Bill into law in preparation for new GM projects.¹³ The enactment of the Bill into law is expected to open doors for new GM crops including Bt cotton and disease tolerant bananas.¹⁴ The banana crop is currently being improved in what is known to be ‘one of the most advanced biotech research laboratories in Africa’ opened by the Uganda government in 2003.¹⁵ Furthermore, Uganda is expected to be the next country after South Africa to introduce Bt cotton, which will allegedly reduce the use of pesticides and increase productivity.¹⁶

Objective of the study

Having noted that South Africa and Uganda have taken different approaches towards the regulation of GMOs, this study examines which of the two regimes provides a satisfactory regime that may be acceptable to other countries in Africa. As a result, this dissertation constitutes a critical and comparative analysis of the contrasting biosafety regimes of South Africa and Uganda.

Outline of the study

The analysis commences with a consideration of key international and regional instruments such as the Convention on Biological Diversity, the Cartagena Protocol on Biosafety and the African Model Law on Safety in Biotechnology.¹⁷ These instruments should set the context for the domestic regulation of biosafety in both South Africa and Uganda.

¹² Mayet, *supra* note 7.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ <http://www.africabiotech.com/news2/article.php?uid=47>.

¹⁶ <http://www.odofin.com/english/examples%204%20using%20biotechnology%20africa.htm>.

¹⁷ *Convention on Biological Diversity* 31 ILM, 818 (1992), *Cartagena Protocol on Biosafety* 39 ILM 1027 (2002), African Model Law on Safety in Biotechnology available at <http://saqa.org.za/ncf/docs/modellaw.html>

The second part of the analysis focuses on South Africa. It provides a brief overview of laws of relevance to biosafety regulation and a detailed critical analysis of the extent to which these laws provide an effective and equitable regulatory approach. An identical enquiry is undertaken for Uganda in the third part of this dissertation.

The dissertation concludes with a comparative analysis of the two countries biosafety regimes. It highlights their similarities and differences; comparative strengths and weaknesses; and aspects requiring urgent reform in order to bring them in compliance with international and regional instruments. This comparison is undertaken under certain key themes, namely: institutional arrangements, decision-making process; risk assessments; public participation; labeling and identification; liability and redress; enforcement and compliance.

CHAPTER 2

KEY CONCEPTS

2.1 Biosafety, Biotechnology and Genetically Modified Organisms.

Biosafety is a rather broad term related to different fields including agriculture, medicine and ecology. This paper focuses on biosafety in the context of agriculture. The Cartagena Protocol, the most important international instrument on biosafety surprisingly does not define the term. However, it may generally be perceived as efforts aimed at reducing and eliminating potential risks resulting from biotechnology and its products.¹⁸ The National Biotechnology and Biosafety Policy of Uganda defines biosafety as; ‘...a collective term that refers to the safe development, transfer and application of biotechnology and its products.’¹⁹ It includes measures used for assessment and management of risks linked to GMOs, mechanisms established to regulate and control potential risks that biotechnology poses to human health, the environment and socio-economic impacts.²⁰ As noted above, there is a close link between biosafety and biotechnology; hence, an understanding of biotechnology is imperative.

Biotechnology refers to ‘the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organism in their natural or modified forms.’²¹ The term has also been defined to mean ‘...any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use.’²² To put it simply, biotechnology provides for the transfer of genetic material between species.²³

¹⁸ <http://www.biodiv.org:680/biosafety/faqs.asp?area=biotechnology&faq=1>.

¹⁹ National Biotechnology and Biosafety Policy, Uganda National Council for Science and Technology, December 2004 at 6.

²⁰ Ibid.

²¹ Wallis E, ‘Fish Genes Into Tomatoes: How the World Regulates Genetically Modified Organisms’ 2004 80 *North Dakota Law Review* at 422 (quoting Reimer P and Schwartz B, *Trade and Genetically Modified Foods: Biotechnology : A Canadian Perspective*, 1 ASPER REV. INT’L BUS & TRADE L. 91, 91 (2000).

²² *Cartegena Protocol on Biosafety*, Frequently Asked Questions on the Biosafety Protocol, available at <http://www.biodiv.org/biosafety/faqs.asp?area=biotechnology&faq=1> See also Art 2 *Convention on Biological Diversity* 31 ILM, 818 (1992).

²³ McGinn K A, Symposium Articles and Note (1999-2000) 12 *Georgetown. International Environmental Law Review* 695 at 695.

The biotechnology industry is acclaimed for benefits such as advancement in medicine and agriculture. Potential benefits of using this type of technology in agriculture include higher yields on less acreage of land, disease and pest resistant varieties and selectivity in acquiring preferred traits.²⁴ On the other hand, skeptics argue that the application of biotechnology in agriculture is potentially risky. It is feared that the modified genes or the transgenes may migrate into non-target organisms, leading to the creation of herbicide resistant weeds or causing adulteration of foods.²⁵ Farmers using genetically modified seeds are required to sign agreements, which forbid them from saving seed. As such, the practice of saving seed and developing seed banks is being threatened.²⁶ Given that a huge number of farmers rely on their seed banks especially for their food needs, any threat to the practice of seed saving could have a devastating outcome.²⁷

Genetically modified crops encourage the practice of mono cropping.²⁸ This practice is a threat to the diversity of traditional agricultural methods that have been applied over time.²⁹ Further, the practice makes crops more susceptible to crop failure in case the crops come under attack.³⁰ A greater diversity of crops is more likely to withstand an attack than uniform crops.³¹ The users of GM crops are also required to pay royalties to the patent holder and yet it is very clear that many poor farmers cannot afford to pay this.³² Surprisingly, the duty to pay royalties appears to extend to persons whose crops have been contaminated by a patented genetically modified gene.³³ In the *Percy Schmeiser case* involving a Canadian farmer, a Canadian court ordered Percy Schmeiser to pay royalties to the patent holder, Monsanto, notwithstanding the fact that his canola crop had been contaminated by that of a third party.³⁴

²⁴ Saigo H, 'Agricultural Biotechnology and the Negotiation of the Biosafety Protocol' (1999-2000) 12 *Georgetown International Environmental Law Review* 779 at 784.

²⁵ Ibid at 787.

²⁶ Barron N, 'A Case of Throwing Caution to the Wind; A Critical Analysis of the EIA Provisions Contained in the Genetically Modified Organisms Act of South Africa.' (2003) 10 *SAJELP* 93 at 100.

²⁷ Ibid.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

³¹ Ibid.

³² Ibid at 101.

³³ Ibid.

³⁴ Ibid at 101-102.

Further, it has been argued that the use of GM crops facilitates dependency of developing countries on the foreign Multi-national companies that supply the seeds such as Monsanto.³⁵ Biotechnology has over the years brought about enormous changes in agricultural practices³⁶ through genetic engineering of crops. Therefore, it poses a great challenge to policymakers globally.³⁷

Genetic engineering is one form of technological advancement in agriculture that is quite ground-breaking.³⁸ Genetic modification is only one of the techniques of modern biotechnology and it is the most highly contested.³⁹ Here, contrary to the conventional methods of plant and animal breeding, there is direct manipulation of genetic material in plants and animals by inserting, removing or altering genes.⁴⁰

GMOs are products of genetic transfer, better yet products of biotechnology.⁴¹ The Cartagena Protocol on Biosafety⁴² and the Convention on Biological Diversity (CBD)⁴³ both make use of the term 'living modified organisms' (LMOs).⁴⁴ LMOs include GMOs therefore; the two terms may be used interchangeably.⁴⁵ The term LMOs was introduced into the CBD language by grain producing countries that sought to evade regulation for their products while accepting only the regulation of living organisms.⁴⁶

GMOs are very controversial arguably because of the potential risks associated with their use. Additionally there is uncertainty surrounding the extent of the potential risks. There

³⁵ Ibid at 102.

³⁶ Teel J, 'Regulating Genetically Modified Products and Processes: An Overview of the Approaches' (1999-2000) 8 *New York University Environmental Law Journal* 649 at 649.

³⁷ Ibid.

³⁸ Falkner R and Gupta A, Implementing the Biosafety Protocol: Key Challenges, Chatham House Briefing Paper No. 4 (London: RIIA, 2004)

³⁹ An Explanatory Guide to the Cartagena Protocol on Biosafety at 7. Available at <http://www.ecoconsult.ch/uploads/1144-Biosafety-guide.pdf>

⁴⁰ Ibid.

⁴¹ Teel, supra note 36.

⁴² 39 ILM 1027 (2002).

⁴³ 31 ILM 818 (1992).

⁴⁴ LMO is defined in Article 3 of the Biosafety Protocol as any living organism that possesses a novel combination of genetic materials contained using modern Biotechnology.

⁴⁵ Birnie and Boyle, *International Law and the Environment*, 2nd Ed, 2002 at 580. For purposes of clarity, the term GMOs will be used throughout this paper.

⁴⁶ *Governing Biotechnology in Africa*, supra note 1.

are economic, environmental and consumer health risks and related benefits associated to the use of GMOs.⁴⁷ The economic benefits include increased yields, reduced net input costs and increased profits.⁴⁸ On the other hand, economic risks associated to their use may include failure of technology to produce anticipated benefits and loss of exports due to increased consumer resistance to GM foods.⁴⁹ Regarding the environment, it has been argued that, GM technologies lessen biodiversity loss and damage as they reduce clearing for agriculture. A serious environmental threat, however, is that modified genes could be transferred to non-GM genes, creating varieties that may threaten biodiversity. With regard to health, proponents promise increased yields that could be used to feed malnourished populations. Yet, it is feared that new allergenic risks may be created from the transgenic transformations.⁵⁰

2.2 The Need for Biosafety Regulation

The purpose of biosafety is to serve as a device for ensuring the safe use of biotechnology products without posing undue risk to human health, the environment, or unnecessary constraints on transfer of technology.⁵¹ Biosafety regulation is a mechanism for the safe use of biotechnology applications into the environment.⁵² According to one commentator, biosafety regulation is instrumental for ensuring the environmental and human safety of GMOs as well as giving people the confidence in GMO products.⁵³ Another commentator observes that regulation in biotechnology, or biosafety regulation for that matter, serves three main functions; ‘risk management, facilitating commercial transactions and generating public trust in new technologies’.⁵⁴ Elsewhere, the functions ascribed to biosafety are said to be three-dimensional: providing choice, ensuring safety and meeting

⁴⁷ Meijer E and Stewart R, ‘The GM Cold War: How Developing Countries Can Go from Being Dominos to Being Players’ (2004)13 3 *RECEIL* at 250- 251.

⁴⁸ *Ibid.*

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ Biosafety Resource Book at 5. Available at <http://www.bio-earn.org/resource%20book/Home.htm>.

⁵² *Ibid.*

⁵³ Jaffe G (2006) A Comparative Analysis of the National Biosafety Regulatory Systems in East Africa. EPT Discussion Paper 146 Available at <http://www.ifpri.org/divs/eptd/dp/papers/eptdp146.pdf>. Jaffe G, Biosafety Regulation in the North and South. Available at http://www.cspinet.net/biotech/biosafety_regulation_ns.pdf.

⁵⁴ Newell P, (1997) Biotechnology and the Politics of Regulation. Available at <http://www.ids.ac.uk/ids/env/PDFs/biotechpaperrev.1Peter1.pdf>.

a country's international obligation.⁵⁵ The one function that runs through all purposes set out by the different sources is safety. One may conclude therefore, that the key purpose of bio-safety is to ensure safety.

2.3 Adequate Biosafety Regulation

It is not an easy task to describe what amounts to adequate regulation in biosafety. This is particularly the case in the light of the different functions that biosafety regulation serves. Biosafety regulation that is adequate in the context of risk management may not necessarily be adequate for purposes of facilitating commercial transactions. Due to differences in traditions and circumstances in the different regions of the world, there appears to be a wide variance in the attitudes towards risks associated with GMOs and their regulation.⁵⁶ For purposes of this paper, an adequate biosafety regulation is construed as a 'protective' one.⁵⁷

A 'protective' biosafety regulatory system is one that safeguards human health and the environment from the risks posed by genetically modified organisms.⁵⁸ Such a system must be functional, meaning that it has to be workable, understandable, equitable, fair, adaptive and enforceable.⁵⁹ Additional characteristics of a functional and protective regulatory system include the need for it to be comprehensive, transparent, participatory, flexible and efficient.⁶⁰ It must have adequate legal authority and it must set clear safety standards, prescribe a proportionate risk based review as well as provide for post approval oversight.⁶¹ It is also worth noting that the existence of biosafety regulation will most often depend on the type of government in a country and its politics, its perception

⁵⁵ Newell P and Mackenzie R, 'The 2000 Cartagena Protocol on Biosafety: Legal and Political Dimensions' (2002) 10 *Global Environmental Change* available at <http://www.gapresearch.org/governance/GEC8.pdf>

⁵⁶ Nelkin D et al, 'The International Challenge of Genetically Modified Organisms Regulation' (1999-2000) 8 *New York University Environmental Law Journal* 523 at 524.

⁵⁷ Jaffe (2006), *supra* note 53 at 2.

⁵⁸ *Ibid.*

⁵⁹ UNEP – GEF BIOSAFETY UNIT 2004 in Jaffe (2006), *supra* note 52 at 2.

⁶⁰ Jaffe (2006), *supra* note 53 at 3-9.

⁶¹ *Ibid.*

of the safety of GMOs, and the country's regulation of food, agriculture and environmental issues.⁶²

The subsequent section considers biosafety regulation under international instruments. A number of World Trade Organization (WTO) Agreements have implications on domestic regulation of biosafety.⁶³ Countries have to take the terms of these into consideration when enacting their domestic legislation. However, the discussion will not cover the trade related aspects of Biosafety regulation. Similarly, the International Plant Protection Convention (IPPC) and the Codex Alimentarius have implications on biosafety regulation although they will not form part of the subsequent discussion.⁶⁴

⁶² Ibid at 2.

⁶³ Sanitary and Phytosanitary (SPS) Agreement GATT Doc. MTN/FA li-A1A-4, 33 ILM XXX; Technical Barriers to Trade (TBT) 18 ILM 1079 (1979); General Agreements in Tariffs and Trade 1994 (GATT) 33 ILM 28 (1994) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 33 ILM 1197 (1994).

⁶⁴ International Plant Protection Convention (IPPC) available at <http://www.ipcc.int/IPP/En/defaults.htm> and the Codex Alimentarius available at <http://www.codexalimentarius.net>.

CHAPTER 3

BIOSAFETY REGULATION UNDER INTERNATIONAL AND REGIONAL INSTRUMENTS

3.1 Introduction

The roots of international biosafety regulation may be traced back to the period between 1970 and 1980 during which problems associated with biotechnology were identified.⁶⁵ This process later culminated into the introduction of a number of international and regional instruments of direct or indirect relevance to biosafety regulation. These include the CBD,⁶⁶ the Cartagena Protocol on Biosafety,⁶⁷ and the African Model Law on Safety in Biotechnology.⁶⁸ These instruments set out rights and obligations to regulate biosafety/biotechnology. Furthermore, they provide for the right and obligation of states to take considerations such as food safety, health, environmental concerns and food security into account when making decisions on the import and use of GMOs.⁶⁹

A discussion on the above cited international instruments is important, as the both Uganda and South Africa are parties to these. Consequently the instruments should have been guided them in developing their domestic legislation. The domestic regimes of the two countries will be assessed against the standards set by the instruments in order to determine the extent of their compliance with such standards.

3.2 Convention on Biological Diversity

The Convention on biological diversity (CBD) is the parent treaty to the Cartagena Biosafety Protocol. The CBD was adopted in May 1992 in Nairobi.⁷⁰ On 5 May 1992, it was opened for signature at the Rio Summit and entered into force on 29 December 1992.⁷¹ The central focus of the CBD is the conservation of biodiversity and equitable

⁶⁵ Biosafety Guide, supra note 39 at 2.

⁶⁶ 31 *ILM* 818 (1992).

⁶⁷ 39 *ILM* 1027 (2002).

⁶⁸ <http://saqa.org.za/ncf/docs/modellaw.html>

⁶⁹ Mackenzie R, 'International Regulation of Modern Biotechnology' at 3 available at <http://www.gapresearch.org/governance/RMregulationfinal.pdf>.

⁷⁰ Biosafety Guide, supra note 39 at 1.

⁷¹ *Ibid*.

distribution of its benefits.⁷² Another force behind the CBD as alluded to by Glazewski is biosafety.⁷³

Three provisions in the CBD relate to biosafety directly or indirectly.⁷⁴ These are Articles 8 (g), 19 (3) and 19 (4). The negotiations for the Biosafety Protocol were based upon the provisions of Article 19(3),⁷⁵ which compels parties to consider the need for a protocol on biosafety.⁷⁶ Articles 8 (g) and 19 (4) of the CBD require parties to maintain, among other things, the means to regulate, control and manage risks associated with the use and the release of GMOs resulting from biotechnology.⁷⁷

The Convention does not set out detailed rules on GMOs other than placing a broad obligation on each party to provide other signatory states with information on the use and safety regulations that handling such organisms require, as well as the potential adverse impacts these GMOs may cause.⁷⁸

3.3 The Cartagena Protocol on Biosafety

3.3.1 Background

The Cartagena Protocol on Biosafety is the first international agreement specifically regulating GMOs.⁷⁹ It was adopted in Montreal 2000 after nearly four years of negotiations.⁸⁰ It entered into force in 2003 after its 50th ratification.⁸¹ The Cartagena Protocol has a wide global ratification.⁸² The Protocol is widely accepted on the African

⁷² Glazewski J, *Environmental Law in South Africa*, 2nd Ed, 2005 at 259.

⁷³ Ibid.

⁷⁴ Biosafety Guide, supra note 39 at 1.

⁷⁵ Kameri Mbote P 'Development of Biosafety Regulations in Africa in the Context of the Cartagena Protocol: Legal and Administrative Issues' (2002) 11 (1) *RECEIL* 62 at 63.

⁷⁶ Article 19.3. Convention on Biological Diversity. (CBD).

⁷⁷ Kameri Mbote, supra note 75.

⁷⁸ Sands P *Principle of International Environmental Law* 2nd Ed 2003 at 522.

⁷⁹ Although the Cartagena Protocol refers to LMOs and not GMOs, for purposes of this paper, the term GMO will be used. See Biosafety Guide, supra note 39.

⁸⁰ Falkner and Gupta, supra note 38 at 2.

⁸¹ Ibid.

⁸² As of January 2007, 139 members have ratified
<http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt>.

continent where 39 countries including South Africa and Uganda have so far ratified.⁸³ The Protocol entered into force in the two countries on 12 November 2003 and 11 September 2004 respectively.⁸⁴

3.3.2 Objective

The Biosafety Protocol aims at specifically dealing with biotechnology.⁸⁵ The Protocol is an international framework that regulates all GMOs.⁸⁶ Its focal point is the transboundary movement of GMOs and their domestic regulation.⁸⁷ It provides as follows:

‘In accordance with the precautionary principle contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of transfer, handling and use of living modified organism resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on the transboundary movements.’⁸⁸

Inclusion of reference to the precautionary principle on the outset of the objective clause is very significant. It ‘declares the precautionary approach to be the basis and the point of reference for the Protocol’.⁸⁹ Therefore, the ‘precautious spirit’ ought to be applied to the provisions of the Protocol in its entirety.⁹⁰ One of the major elements of the objective of the Protocol is to ‘contribute to ensuring an adequate level of protection’.⁹¹ The Protocol does not attempt to set an absolute standard. However, it seeks to establish supplementary protection where protection is already being taken under other forms and frameworks.⁹² The presumption therefore, is that additional action is being taken or needs to be taken in

⁸³ South Africa ratified on 14 August 2003 and Uganda on 30 November 2001. Ibid.

⁸⁴ Ibid.

⁸⁵ Kameri Mbote, *supra* note 75 at 62.

⁸⁶ Adler J, ‘The Cartagena Protocol and Biological Diversity: Biosafe or Bio-sorry?’ (1999-2000) 12 *Georgetown International Environmental Law Review* 761 at 770.

⁸⁷ Mackenzie, *supra* note 69 at 8.

⁸⁸ Article 1 Biosafety Protocol.

⁸⁹ Biosafety Guide, *supra* note 39 at 31.

⁹⁰ Ibid.

⁹¹ Ibid at 32. See Article 1 Biosafety Protocol.

⁹² Biosafety Guide, *supra* note 39 at 32.

addition to the protection under the Protocol.⁹³ The level of protection envisaged is ‘adequate’ and this subject to interpretation.⁹⁴ This means that the level of protection will depend on the activity undertaken and the nature of risks envisaged.⁹⁵

In developing countries many of which are still in the process of developing their Biosafety laws, it is doubtful whether the Protocol would render supplementary protection. Rather, it forms the basis upon which states seek to establish their Biosafety laws. As a result, it is questionable whether the objective of the Protocol to provide supplementary protection is being achieved in these countries.

3.3.3 Scope

The scope of the Protocol was one of the heavily debated areas during the negotiation process.⁹⁶ This debate centered on finding an appropriate definition for GMOs. This definition would determine the products to be regulated under the Protocol.⁹⁷ While one group led by the United States argued for a narrow definition, involving genetically engineered organisms that are going to be released (for instance plants), other countries argued for a more inclusive definition; one that included all GMOs and their products.⁹⁸ The Protocol’s provisions consequently reflect a compromise.⁹⁹

The Protocol applies to all GMOs that may adversely effect on the conservation and the sustainable use of biological diversity. It applies to their transboundary movement,¹⁰⁰ transit, handling and use.¹⁰¹ This provision in effect spells out the activities to which the Protocol applies. It also specifies the subject matter or the organism to which the Protocol

⁹³ Ibid.

⁹⁴ Ibid.

⁹⁵ Ibid.

⁹⁶ Sagio H, ‘Agricultural Biotechnology and the negotiation of the Biosafety Protocol (1999-2000) 12 *The Georgetown International Environmental Law Review* 779 at 812.

⁹⁷ Ibid

⁹⁸ Ibid.

⁹⁹ Ibid.

¹⁰⁰ Article 3 (k) Transboundary movement ‘means the movement of a living modified organism from one Party to another Party, save that for purposes of Articles 17 and 24 transboundary movement extends to movement between parties and non-parties.

¹⁰¹ Article 4 Biosafety Protocol.

applies; that is GMOs.¹⁰² Although ‘transit, handling and use’ are not defined in the Protocol, transboundary movement is defined and it envisages both intentional and unintentional movement.¹⁰³

Pharmaceuticals are excluded from the scope of the Protocol.¹⁰⁴ In order for the exclusion to apply, three conditions must however prevail. First, there must be a transboundary movement of GMOs; the GMOs in question must be pharmaceuticals for humans; and thirdly, other international instruments must address the GMOs in question.¹⁰⁵ Notwithstanding this exclusion, the Protocol acknowledges the right of a party to subject all GMOs to risk assessment preceding any decision on imports.¹⁰⁶ The advanced informed agreement procedure¹⁰⁷ will not apply to such GMOs however; the GMOs will be subject to the risk assessment provisions and other provisions of the Protocol.¹⁰⁸ The key international organization envisaged in this respect is the World Health Organization.¹⁰⁹

3.3.4 Advanced Informed Agreement

The advance informed agreement (AIA) is the central mechanism, which regulates the transboundary movement of GMOs.¹¹⁰ This procedure, which is the ‘governance mechanism’ of the Biosafety Protocol, has its origins in the notion of ‘prior informed consent’ a renowned international environmental law principle.¹¹¹ The argument for requiring an AIA is that governments reserve the right to know what crosses borders into their territory in order to ensure that the importation of new plants or animal species will

¹⁰² Article 3 (g) Living modified organism ‘means any living organism that possesses a novel combination of genetic material obtained through the use of modern technology’.

¹⁰³ Biosafety Guide, supra note 39 at 53.

¹⁰⁴ Article 5 Biosafety Protocol.

¹⁰⁵ Biosafety Guide, supra note 39 at 56.

¹⁰⁶ Article 5 Biosafety Protocol.

¹⁰⁷ The advanced informed agreement procedure explained in more detail in section 3.2.4 below.

¹⁰⁸ Biosafety Guide, supra note 39 at 56.

¹⁰⁹ Ibid at 55.

¹¹⁰ Mackenzie, supra note 69 at 8.

¹¹¹ Gupta A. ‘Advanced Informed Agreements: A shared Basis for Governing Trade in Genetically Modified Organisms?’ (2001-2002) *Indiana Journal of Global Legal Studies*. 265 at 265.

not cause environmental harm.¹¹² The Protocol provides for an AIA procedure in respect of transboundary movement of GMOs intended for direct introduction into the environment.¹¹³ It requires that prior to the first intentional transboundary movement of GMOs, which are subject to the AIA procedure, the importing party must be notified of the intended movement and given an opportunity to decide whether to import the GMO and furthermore, whether to impose certain conditions if necessary.¹¹⁴

The AIA procedure incorporates the precautionary principle. Accordingly, decisions made during the AIA procedure have to be based on the precautionary approach. It states that:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organisms on the conservation and sustainable use of biological diversity in the party of import, taking into account risks to human health, shall not prevent the party from taking a decision, as appropriate, with regard to the import of the living modified organism...in order to avoid or minimize such potential adverse effects.¹¹⁵

The language of the Protocol in this regard appears to be equivocal. Different interest groups have sought to interpret it in a manner that suits their interests. The European Union and the developing world have hailed the inclusion of this provision as the most noteworthy contribution of the Biosafety Protocol.¹¹⁶ On the contrary, the United States and other representatives of the Biotechnology industry assert that the language of the Protocol does not go further than the discretion permitted to importers of risky products under the WTO regimes and its SPS Agreement.¹¹⁷ Clearly, there is no uniform interpretation of the principle. Ultimately, each state determines whether to apply and how to apply the principle. This renders the application of the principle almost nugatory.

¹¹² Adler J, 'More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol' (2000) 35 *Texas International Law Journal* 173 at 192

¹¹³ Article 7 Biosafety Protocol. The AIA procedure is set out Articles 8,9,10 and 12 with respect to GMOs intended for direct introduction into the environment.

¹¹⁴ Biosafety Guide, *supra* note 39 at 64.

¹¹⁵ Article 10.6 Biosafety Protocol.

¹¹⁶ Gupta A, 'Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?' (2000-2001) 9 *Indiana Journal of Global Legal Studies* 265 at 276.

¹¹⁷ *Ibid.*

Other provisions of the Protocol are equally relevant to the AIA procedure. Before any decision on importation is taken under the procedure, a risk assessment must be carried out.¹¹⁸ The National Competent Authorities are responsible for handling matters during the AIA procedure.¹¹⁹ The Protocol permits the notifier to identify information that should be treated as confidential by the importing party under the AIA procedure.¹²⁰ When making a decision on imports under the AIA procedure, the party of import may take into account socio-economic considerations.¹²¹ The Protocol details the information required in notifications¹²² and the details for risk assessment.¹²³

The AIA procedure does not apply to GMOs intended for direct use as FFP as noted earlier. Parties are obligated to inform the Biosafety Clearing House of a decision regarding GMOs intended for direct use as FFP within 15 days of making such a decision.¹²⁴ The combination of the AIA procedure and the precautionary principle enables countries to reject the importation of certain GMOs, whose safety they are uncertain about because of insufficient scientific evidence following risk assessment.¹²⁵

3.4.5 Risk Assessment

It is important to assess risk in order to identify and evaluate the possible adverse effects of GMOs on the conservation and sustainable use of biological diversity and human health.¹²⁶ This is often necessary at various stages in the development and use of GMOs.¹²⁷ Additionally, risk assessment is important since it helps in decision-making and is regarded by some commentators as ‘the backbone of the decision making process.’¹²⁸ Risk assessment is the key element of the AIA procedure.¹²⁹ However, it does

¹¹⁸ Article 15.2 Biosafety Protocol.

¹¹⁹ Article 19 Biosafety Protocol.

¹²⁰ Article 21.1 Biosafety Protocol.

¹²¹ Article 26 Biosafety Protocol.

¹²² Notifications under Articles 8, 10, and 13 Biosafety Protocol.

¹²³ Information for notification set out in Annex I and details for risk assessment in Annex III Biosafety Protocol.

¹²⁴ Article 11.1 Biosafety Protocol.

¹²⁵ Kameri-Mbote, *supra* note 75 at 63.

¹²⁶ Biosafety Guide, *supra* note 39 at 217.

¹²⁷ *Ibid.*

¹²⁸ Kameri Mbote, *supra* note 75 at 63.

¹²⁹ Newell and Mackenzie, *supra* note 55 at 1.

not only occur in the context of the AIA procedure¹³⁰ but also in the context of GMO intended for FFP.¹³¹

The Protocol makes provision for risk assessment where it states that risk assessments must to be undertaken in a manner that is ‘scientifically sound’, in accordance with Annex III to the Protocol and recognized risk assessment techniques.¹³² Annex III contains detailed guidance on the application of the risk assessment.¹³³ It sets down certain principles, for example; the need for the risk assessment to be carried out in an approach that is scientifically sound and transparent; the need to consider the risks in the perspective of risks posed by non-modified parental organisms; and the need to conduct the risk assessment on a case-by-case basis.¹³⁴ The Annex further describes the methodologies for risk assessments, including generic steps common to risk assessment frameworks.

It is argued that the guidance provided by Annex III is generally consistent with accepted principles and methodology for risk assessment notwithstanding that the specific description and terminology of the steps in risk assessment differ among frameworks. Risk assessment was one of the controversial issues during the negotiations of the protocol which controversy centered on the inclusion of the precautionary principle and socio economic consideration in decision-making.¹³⁵

3.3.6 Risk Management

Risk management is an important tool used to regulate, control and manage the risks identified under the risk assessment procedure.¹³⁶ The Protocol provides for management

¹³⁰ Ibid.

¹³¹ Under Article 11 Biosafety Protocol.

¹³² Article 15 Biosafety Protocol.

¹³³ Hill R et al ‘Risk Assessment and Precaution in the Biosafety Protocol’ (2004) 13 (3) *RECEIL* 263 at 266.

¹³⁴ Ibid.

¹³⁵ Burgiel S, ‘The Cartagena Protocol on Biosafety: Taking the steps from Negotiations to Implementation’ (2002) 11 (1) *RECEIL* 53, at 55.

¹³⁶ Biosafety Guide, *supra* note 39 at 111.

of risks identified in the risk assessment procedure under the Protocol.¹³⁷ Parties are required not only to establish, but also to maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk management provisions of the protocol.¹³⁸ As one of the risk management measures, the Protocol requires each party to ensure that living modified organisms both imported and locally developed undergo a period of observation proportionate to its life cycle. This has to be done before the GMOs are put to use.¹³⁹

3.3.7 The Precautionary Principle

This principle has its origins in the rise of environmentalism in Germany. It is often invoked in respect of wide ranging environmental issues including environmental protection, hazardous wastes and GMOs.¹⁴⁰ The most often cited definition of the principle is enshrined in the Rio Declaration,¹⁴¹ which provides that:

‘...where there are threats of serious irreversible damage, lack of full scientific certainty will not be used as a reason for postponing taking cost-effective measures to prevent environmental degradation.’¹⁴²

The Protocol provides for the right of parties to take decisions based on the precautionary principle.¹⁴³ Accordingly, ‘lack of scientific certainty shall not prevent countries from barring the importation of GMOs.’¹⁴⁴ The Protocol applies precaution to biodiversity as well as the risks to human health.¹⁴⁵ The preamble and Article 1 setting out the objectives of the Protocol both refer to the precautionary principle.

¹³⁷ Article 16 Biosafety Protocol.

¹³⁸ Ibid.

¹³⁹ Article 16.3 Biosafety Protocol.

¹⁴⁰ Boutillon S, ‘The Precautionary Principle: Development of an International Standard’ (2001-2002) 23 *Michigan Journal of International Law* 429 at 430, 433.

¹⁴¹ Rio Declaration, *supra* note 14.

¹⁴² Principle 15 Ibid.

¹⁴³ Under Articles 10.6 and 11.8 Biosafety Protocol.

¹⁴⁴ Adler J, ‘More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol’ (2000) 35 *Texas International Law Journal* 173 at 193.

¹⁴⁵ Biosafety and the Environment; An Introduction to the Cartagena Protocol on Biosafety at 6 available at <http://www.biodiv.org/doc/press/presskits/bs/cpbs-unep-cbd-en.pdf>

A major problem underlying the application of the precautionary principle in biosafety is the potential conflict between environmental protection and economic protection.¹⁴⁶ It is argued concerning the precautionary principle in the Protocol that, its inclusion does not amount to an obligation on the parties.¹⁴⁷ Rather it is a guarantee of the right to do so. This view is plausible given that the Protocol does express the principle in terms that are somewhat different from its original expression in the Rio Declaration. Furthermore it is worth noting that the inclusion of this principle in the Protocol was subject of intense contention during the negotiations.¹⁴⁸ The ‘Like-Minded’ group, comprising mainly developing countries advocated for the inclusion of the precautionary principle to guide decision-making. The ‘Miami Group’ including the likes of the United States and Canada, argued against the inclusion of the principle in decision-making.¹⁴⁹

3.3.8 Socio-economic Considerations

Integrating socio-economic consideration in biosafety decision-making is acknowledged as a major challenge.¹⁵⁰ Nonetheless, it is imperative that this takes place given the numerous socio-economic considerations associated with the development, release and use of these organisms. Relevant concerns include: the potential for GM strains to contaminate organic strains; competition between traditional organic crops and their GM counterparts; the impact on traditional seed stocking activities; the burden created to farmers by the intellectual property rights associated with the GM crops; and the financial burden of having to purchase seeds, pesticides and herbicides from the Multinational seed companies.¹⁵¹

¹⁴⁶ Dommelen, A. van (2000), ‘The Precautionary Principle: Dealing with controversy.’ *Biotechnology and Development Monitor*, No. 43, at 8-11

¹⁴⁷ Hill, *supra* note 133 at 266.

¹⁴⁸ Mackenzie, *supra* note 69 at 3-4.

¹⁴⁹ *Ibid.*

¹⁵⁰ Fransen L, et al, Integrating Socio-Economic Considerations in Biosafety Decision Making: the Role of Public Participation. WRI White paper, at 41 available at http://pdf.wri.org/fransen_lavina_biosafetywhitepaper.pdf.

¹⁵¹ *Ibid* at 10-21.

The Protocol provides, in rather discretionary terms, that parties ‘may’ take into account socio-economic considerations in reaching decisions under the Protocol.¹⁵² Article 26 suggests that not all socio-economic considerations will be taken into account, rather, only those that arise from the impact of GMOs on biological diversity.¹⁵³ When taking into account socio-economic considerations, parties are obliged to comply with their other international obligations.¹⁵⁴ These would include obligations under the WTO Agreements such as the SPS; TBT; and GATT.¹⁵⁵ This provision was inserted following concerns that including socio-economic considerations in decision-making on GMO imports might create trade barriers.¹⁵⁶ The Protocol does not give guidance on how socio-economic considerations are to be taken into account for instance procedure for assessing socio-economic impacts in risk assessments.¹⁵⁷ Further, conditions such as ‘compliance with other international obligations’, water down the provision.

3.3.9 Public Awareness and Participation

Public participation and transparency in decision-making are acknowledged as vitally important components of good governance and sustainable development.¹⁵⁸ It is important that the views of all stakeholders be taken into account in decision-making through a meaningful and well-informed public participation process.¹⁵⁹ Biosafety decisions, such as those relating to the release of GMOs into the environment, may affect the public in those areas where these trials take place.

The Biosafety Protocol provides for public awareness and participation.¹⁶⁰ It exhorts parties to promote and facilitate public awareness, education and participation in dealing with GMOs.¹⁶¹ The language of the provision appears to be ‘soft’ as it does not impose a mandatory obligation on parties to make information available to the public or provide

¹⁵² Article 26.1 Biosafety Protocol.

¹⁵³ Biosafety Guide, *supra* note 39 at 163.

¹⁵⁴ Article 26.1. Biosafety Protocol.

¹⁵⁵ *Supra* note 62.

¹⁵⁶ Biosafety Guide, *supra* note 39 at 164.

¹⁵⁷ *Ibid* at 165.

¹⁵⁸ Petkova et al., 2002 in Fransen et al, *supra* note 150 at 30.

¹⁵⁹ *Ibid*.

¹⁶⁰ Article 23 Biosafety Protocol.

¹⁶¹ Fransen et al., *supra* note 150 at 30.

for public participation. Rather parties are required to ‘promote and facilitate’, access to information and public participation.¹⁶² This is concerning.

3.3.10 Handling, Identification and Packaging

Labelling of food products has long been a cause of legal debate mainly due to the health implications and trade implications.¹⁶³ Labeling is important especially because it enables the consumer exercise their choice and their right to know what they are purchasing.¹⁶⁴

The Biosafety Protocol provides for handling, transport, packaging and identification of GMOs.¹⁶⁵ It obliges parties to ensure that GMOs that are subject to transboundary movement are handled, packaged and transported under safe conditions taking into account relevant international rules and standards.¹⁶⁶ Additionally, it requires parties to ensure that GMOs intended for FFP are accompanied by documentation identifying the GMOs and providing contacts of persons responsible for their movement.¹⁶⁷ The language of the Protocol is rather ambiguous as far as it requires GMOs intended for FFP to be marked ‘may contain’ GMOs.¹⁶⁸ Hence, the Biosafety Protocol has no mandatory provision for labeling.¹⁶⁹

This position reflects a compromise that the negotiating parties agreed to after having disagreed on the issue of labeling. Notably, at the third meeting of the parties to the Cartagena Protocol held in March 2006 in Brazil, it was agreed that, parties would from then on require a label stating ‘contains GMOs’ instead of the former.¹⁷⁰

¹⁶² Biosafety Guide *supra* note 39 at 150.

¹⁶³ Sand H.P, ‘Labelling Genetically Modified Food: The Right to Know’ (2006) 15 (2) *RECEIL* 185 at 186.

¹⁶⁴ Mayet M, ‘Why Do We need to Label Genetically Modified Food Products?’

¹⁶⁵ Article 18 Biosafety Protocol.

¹⁶⁶ Article 18.1. Biosafety Protocol.

¹⁶⁷ Biosafety Guide, *supra* note 39 at 125, see also Article 18.2 Biosafety Protocol.

¹⁶⁸ Article 18.2 (a) Biosafety Protocol.

¹⁶⁹ David et al, *supra* note 3 at 308.

¹⁷⁰ Sand, *supra* note 163 at 188.

3.3.11 Liability, Redress and Compensation

GMOs are considerably different from other products insofar as they are likely to intermingle with other wild organisms when introduced into the environment.¹⁷¹ Their introduction into the environment therefore raises many concerns. For instance, the potential for transgenic varieties to out-perform other varieties leading to the displacement of wild species; and the potential for the contamination of organic species by transgenic seeds.¹⁷² Liability for damage caused by GMOs ought to be viewed in a broad context, which takes into account the property rights attached to these organisms.¹⁷³ GMOs are often protected by intellectual property rights, largely patents and can only be used with permission.¹⁷⁴ In practice however, GMOs that have been introduced into the environment often go beyond the environment in which they have been introduced. Where the patented organism is a seed and such seed finds their way into the lands of a farmer who does not grow transgenic crops, and therefore, does not pay royalties to the company holding the patent, the patent holder may claim for infringement of the patents.¹⁷⁵

It is no surprise, therefore, that many countries set very stringent regulation when it comes to the use or release of GMOs or products containing GMOs.¹⁷⁶ The situation is exacerbated by the fact that there is so much uncertainty about their potential impact and it cannot currently be entirely ruled out that these impacts are hazardous.¹⁷⁷ Liability and redress is one legal response to harm arising from legal or illegal activities relating to GMOs.¹⁷⁸ Liability rules may serve three potential functions: prevention, reparation, or correction.¹⁷⁹

¹⁷¹ Cullet P 'Liability and Redress for Modern Biotechnology' (2006) 15 *Yearbook of International Environmental Law* 165-195 at 168.

¹⁷² Cullet P 'Liability and GMOs: Towards a Redress Regime in Biosafety Protocol' (2004) 39/7 *Economic and Political Weekly* 615 at 616.

¹⁷³ Ibid.

¹⁷⁴ Ibid.

¹⁷⁵ *Monsanto Canada Inc v Schmeiser (CA)*, September 4, 2002, [2003] 2FC 165. In this Canadian case, the court ruled that the farmer, Schmeiser was liable to pay Monsanto the owner of the patented seed whether he was aware of the presence of the seed in his field or not.

¹⁷⁶ Cullet, supra note 171.

¹⁷⁷ Ibid.

¹⁷⁸ Ibid.

¹⁷⁹ Duall E, 'A Liability and Redress Regime for Genetically Modified Organisms under the Cartagena Protocol' (2004) 36 (1) *George Washington International Law Review* 173 at 192.

Liability under the Biosafety Protocol was one of the highly contested issues during the negotiations with developing countries pushing for a system of liability and redress in the event of harm caused by GMOs.¹⁸⁰ The developing countries wanted clear rules regarding who can claim compensation, from whom and for what type of damages, GMOs may cause to the environment, human health and socio-economic interests.¹⁸¹ This demand was however rejected by the developed countries. Consequent to the disagreement surrounding this issue, the provisions of the Protocol relating to Liability and Redress, reflect a compromise.¹⁸² The Protocol does not provide a liability regime; rather, parties agreed to adopt a process at the first Conference of the Parties (COPs).¹⁸³

Following the first meeting of the COPs, held in Kuala Lumpur early 2004, some progress was noted. Parties agreed that an *ad hoc* working group of legal and technical experts would commence work and present their final report on proposed international rules and procedures by 2007.¹⁸⁴ The failure of the Protocol to provide a liability and redress regime is undoubtedly one of its major flaws.

3.3.12 Confidential Information

During the negotiations of the Protocol, a number of countries lobbied for a clause on confidential information to be included.¹⁸⁵ Their justification was that information provided to importing countries during AIA procedures might contain confidential proprietary information. This view met opposition from those of the belief that constraint on disclosure would hamper the ability of parties to deal with emergencies involving GMOs. Consequently, Article 21 reflects the compromise and it permits certain information to be treated as confidential. It specifies in broad terms, the general procedure for ensuring protection of confidential information and sets out a broad obligation to protect confidential information received under the Protocol, for instance;

¹⁸⁰Falkner and Gupta supra note 38 at 10.

¹⁸¹ Ibid.

¹⁸² Biosafety Guide supra note 39 at 167.

¹⁸³ Article 27 Biosafety Protocol.

¹⁸⁴ Falkner and Gupta, supra note 38 at 10.

¹⁸⁵ Biosafety Guide, supra note 39 at 137.

information obtained in accordance with Annex I;¹⁸⁶ or information acquired during the AIA procedure.¹⁸⁷ The type of information that should not be subject of confidentiality is also specified and it includes; the name and address of the notifier (the party providing information); a general description of the living modified organisms; a summary of the risk assessment; and methods and plans for emergency response.¹⁸⁸

It is noted that while Article 21, makes provision for certain information to be treated as confidential, this requirement is not tantamount to a general rule.¹⁸⁹ The discretion is on the notifier to specify the information they consider should be treated confidential and then to consult with the party of import. Although the notifier is required to justify why the information in question should be treated as confidential, the Protocol does not specify what is required in terms of justification for confidentiality.¹⁹⁰

3.4 The African Model Law on Safety in Biotechnology:

The former Organization of African Unity (OAU) adopted the African Model Law¹⁹¹ in 2001 to cater for biosafety in Africa in reaction to concerns about the adverse effects of biotechnology on human health, biodiversity and the environment.¹⁹² The African Model law uses the discretion given to the parties under the Biosafety Protocol, to adopt more protective measures than the agreed minimum set out in the Protocol.¹⁹³ Although the Model Law is not legally binding, African states are, however, encouraged to rely on its provisions when enacting their domestic laws in an attempt to harmonize existing and future domestic biosafety regulation in Africa.¹⁹⁴ It is argued that the adoption of this law will enable governments to enact biosafety regulations that are based on a broad and unified framework.¹⁹⁵ This Law is of significant relevance therefore when considering the

¹⁸⁶ Annex I sets out minimum information required in notifications under Articles 8, 10 and 13.

¹⁸⁷ Biosafety Guide, supra note 39 at 138.

¹⁸⁸ Article 21. 6 Biosafety Protocol.

¹⁸⁹ Biosafety Guide, supra note 39 at 138.

¹⁹⁰ Ibid.

¹⁹¹ African Model Law on Safety in Biotechnology Available at <http://saqa.org.za/ncf/docs/modellaw.html>

¹⁹² The Preamble to the Model Law.

¹⁹³ Mayet M 'Why Africa should adopt the African Model Law on Safety in Biotechnology' (2004) 11 (2) *SAJELP* 195 at 196.

¹⁹⁴ Ibid at 195.

¹⁹⁵ Ibid.

biosafety regimes in South Africa and Uganda. The subsequent section will briefly highlight key aspects of the Model Law.

3.4.1 Scope

The ambit of the African Model Law is far broader than that of the Biosafety Protocol. It applies to the import, export, transit, contained use, release and placing on the market of all GMOs and GMO products regardless of whether they are intended for release into the environment, for use as pharmaceuticals, or for FFP.¹⁹⁶ The Model Law sets up uniform provisions, which apply to all these activities because it views the risks from GMOs as being the same whether being used in agriculture medicine or research.¹⁹⁷

3.4.2 Advanced Informed Agreement

The Model Law contains provisions on the AIA. It sets out the different GMO related activities that require prior consent including import, transit and contained use.¹⁹⁸ The AIA envisaged under the Model Law is similar to the one in the Biosafety Protocol in the sense that it applies to the transboundary movement of genetically modified organisms. However, the AIA under the Model Law has a wider scope of application as it also applies to all GMOs and their related activities. Under the Protocol, the AIA does not apply to certain GMOs such as those intended for contained use as noted earlier.¹⁹⁹ Article 4 of the Model Law expressly states that,

‘No person shall import, transit, carryout the contained use of or release of a genetically modified organism or a product of a genetically modified organism without an advanced informed agreement or the explicit written approval of a competent authority whichever is appropriate.’

¹⁹⁶ Article 2 African Model Law.

¹⁹⁷ Mayet, *supra* note 193 at 201.

¹⁹⁸ Article 4 African Model Law.

¹⁹⁹ Article 6.1, 6.2 and 7.3 Biosafety Protocol.

Evidently, the Model Law requires the prior informed consent of importing countries, which may only be given subsequent to a risk assessment having been undertaken.²⁰⁰

3.4.3 Precautionary Principle

The precautionary principle is far more strictly incorporated in the Model Law than in the Biosafety Protocol.²⁰¹ Accordingly, no approvals are to be made unless there is enough evidence to prove that the GMOs do not pose any serious danger to human health, the environment and biodiversity.²⁰² Similarly, where risk assessment indicates that risk cannot be avoided, approval for use, import or any other use is to be denied.²⁰³ The application of the precautionary principle therefore permeates both risk assessment and decision-making.

3.4.4 Public Participation

Public participation is comprehensively provided for in the Model Law.²⁰⁴ It stresses that the time within which the public is expected to comment must be long enough to ensure meaningful public reaction.²⁰⁵ In addition, the Model Law affords competent authorities a wide discretion to determine on a case-to-case basis, the time within which the public is to comment.²⁰⁶ More importantly, public comments must be taken into account by the competent authority in decision-making.²⁰⁷ The provisions guarantee access to crucial information concerning GMOs.²⁰⁸ Access to information on approvals granted and denied relating to contained use, release or placing on the market is guaranteed. In addition, competent authorities must make risk assessment reports available to the public.²⁰⁹

²⁰⁰ Mayet, *supra* note 193 at 208.

²⁰¹ *Ibid* at 207.

²⁰² Article 6.7 African Model Law.

²⁰³ Article 8.5 African Model Law.

²⁰⁴ Article 5 African Model Law.

²⁰⁵ Article 5 African Model Law.

²⁰⁶ Article 5.3 African Model Law.

²⁰⁷ Article 5.4 African Model Law.

²⁰⁸ Article 5.5 African Model Law.

²⁰⁹ *Ibid*.

3.4.5 Labelling and Identification

According to Kiss and Shelton, labelling requirements are not a new phenomenon in the context of food safety. They have previously been used to specify information on the nutritional content of foods and the proper use and hazards of cleaning products.²¹⁰ Hence, labelling not only provides information on the product, it also acts as a tool for managing risks.²¹¹ Unlike the Biosafety Protocol, the Model Law addresses the issue of labelling in very clear and precise terms. Article 11 states that GMOs and their products should be labelled and identified in such a manner to indicate that they are GMOs. In addition, sufficient information must be included for purposes of traceability.

3.4.6 Liability and Redress

GMOs are very complex and hold the potential for causing substantial damage. Clearly defined provisions for liability and redress are therefore essential. Unlike the Biosafety Protocol, the Model Law extends liability to the supplier and developer of a GMO in addition to the end user.²¹² Besides extending liability to suppliers and developers, the Model Law also prescribes strict liability.²¹³ The determination of the liability of the responsible party will therefore not be dependant on fault.

The Model Law also addresses issues of redress, specifically compensation. It states for instance, that in case of damage to the environment, compensation will include clean up, rehabilitation and reinstatement costs.²¹⁴ The Model Law grants legal standing to persons or groups of persons who want to sue in the public interest.²¹⁵ In addition, provision is made for exonerating applicants from potential legal cost orders if the applicants are unsuccessful.²¹⁶ The liability provisions in the Model Law are particularly essential in the African context where the use of GMOs and GM products are on the increase.²¹⁷

²¹⁰ Kiss A and Shelton D, *International Environmental Law* 3rd Ed 2004 at 267.

²¹¹ Glowka in Mayet, *supra* note 193 at 211.

²¹² Article 14.2 African Model Law.

²¹³ Article 14.1 African Model Law.

²¹⁴ Article 14.5 African Model Law.

²¹⁵ Article 14.7 African Model Law.

²¹⁶ Article 14.8 African Model Law.

²¹⁷ Mayet, *supra* note 193 at 212.

3.5 Conclusion

The Biosafety Protocol, which is the most important international instrument on biosafety, does lay down minimum standards for biosafety and imposes broad obligations on party states. The broad obligations and the generally minimum standards may be attributed to the several competing interest that were represented during its negotiation. Accordingly, it reflects a compromise. Its major weakness is arguably the failure to provide a liability and redress mechanism.²¹⁸ In addition, although the Protocol provides for risk assessment, it has no discussion on what level of safety is adequate before the approval of a GMO.²¹⁹ Further, it makes no suggestion as to how much potential risk must be identified to justify withholding of consent.²²⁰ The Protocol does not provide for what happens after a risk assessment is conducted and potential risks are identified. It leaves the discretion to each country to decide what safety standards they believe must be satisfied before consenting to the use or importation of a GMO.²²¹ As far as socio economic considerations are concerned, the Protocol provides in weak terms that these may be taken into account but does not specify how these are to be included in the procedures under the Protocol.²²² Not all major risks associated with GMOs are comprehensively addressed by the Protocol. It does not address substantially human health related or food safety concerns surrounding GMOs. It is noted that these are arguably greater concerns than biodiversity risks.²²³ The greatest strength of the Protocol is arguably, the endorsement of the precautionary principle.²²⁴ In enacting their domestic legislation on biosafety, parties are expected to rely on the standards set by the Protocol. However, the Protocol gives states discretion to enact rules that are more stringent.²²⁵

The African Model Law on the other hand, is more comprehensive and deals far more robustly with most of the controversial issues in biosafety regulation. Some of its strong

²¹⁸ Jaffe (2006), supra note 53 at 13.

²¹⁹ Ibid.

²²⁰ Ibid.

²²¹ Ibid.

²²² Ibid.

²²³ Ibid.

²²⁴ Ibid at 12.

²²⁵ Article 2.4 Biosafety Protocol.

points are: the inclusion of the precautionary principle; provision for comprehensive risk procedures; and the inclusion of a clear and extensive redress regime.²²⁶

The subsequent sections will now consider and compare the adequacy of South Africa and Uganda's biosafety regimes. This will be done in the context set out by the foregoing discussion of biosafety under international instruments. Therefore the discussion will adopt the key themes previously discussed which include; scope, risk assessment and management, liability and redress, public participation and socio-economic considerations when undertaking a critique of the two regimes.

²²⁶ Mayet, *supra* note 193 at 212.

CHAPTER 4

AN OVERVIEW OF SOUTH AFRICA'S BIOSAFETY REGIME

4.1 Introduction

The relevant framework for biosafety regulation in South Africa consists of a fragmented array of framework and sectoral laws.²²⁷ These include: the Constitution of the Republic of South Africa;²²⁸ the Genetically Modified Organisms Act and their Regulations;²²⁹ the Genetically Modified Organisms Amendment Bill;²³⁰ the Promotion of Access to Information Act;²³¹ the Promotion of Administrative Justice Act;²³² the National Environmental Management Act;²³³ the Foodstuffs, Cosmetics and Disinfectants Act;²³⁴ and the National Environmental Management Biodiversity Act.²³⁵ In addition, several other policy documents are relevant in the context of biosafety regulation such as; Draft Biosafety Policy;²³⁶ Agricultural Biotechnology Strategy;²³⁷ GMO Guidelines (Advisory Committee);²³⁸ and GMO Guidelines.²³⁹ This section provides an overview of these relevant laws and their relevance to biosafety.

4.2 Principal Legislation

4.2.1 The Genetically Modified Organisms Act

The Genetically Modified Organisms Act (hereinafter the GMO Act),²⁴⁰ is the main law that regulates GMOs in South Africa. The Act does not contain a section that explicitly

²²⁷ Feris L 'Risk Management and Liability for Environmental Harm Caused by GMOs – The South African Regulatory Framework. Unpublished Article 2006.

²²⁸ Act 108 of 1996.

²²⁹ GMO Act No 15 of 1997. The GMO Regulations, GNR 1420 of 1999.

²³⁰ GN 27913 of 2005.

²³¹ No 2 of 2000.

²³² No 3 of 2000.

²³³ No 107 of 1998.

²³⁴ No 54 of 1971.

²³⁵ No 10 of 2004.

²³⁶ Notice 1576 of 2005.

²³⁷ Notice 1591 of 2005.

²³⁸ Notice 1047 of 2004.

²³⁹ Notice 1046 of 2004

²⁴⁰ GMO Act, *supra* note 229.

states what its objectives are. Rather these are couched in its preamble,²⁴¹ which provides that the GMO Act is intended to ‘promote the responsible development, production, use and application of genetically modified organisms.’²⁴² The GMO Act applies to a range of activities including the genetic modification of organisms, development, production, release, use and application of genetically modified organisms and use of gene therapy.²⁴³ However, it excludes certain activities such as techniques involving human gene therapy.²⁴⁴

The Act establishes a number of institutions to undertake its administration and implementation. These are the Executive Council of Genetically Modified Organisms (the Council), the Advisory Committee and the office of the Registrar.²⁴⁵ The Council is charged with the role of advising the Minister and making decisions concerning granting of permits.²⁴⁶ The Advisory Committee is the national advisory body on all matters concerning GMOs.²⁴⁷ The registrar plays an administrative role including the issuing of permits.²⁴⁸

As far as enforcement is concerned, the Act provides for inspectors who are empowered to enter premises and carry out inspection for purposes of ensuring that the Act is being observed.²⁴⁹ The Act contains some obscure provisions entitled ‘determination of risks and liability’ that attempt to set out the liability and risk management regime.²⁵⁰ In addition, the Act provides for offence and penalty provisions.²⁵¹ The Minister is specifically empowered to prohibit any activities involving GMOs on the

²⁴¹ Mayet M, ‘Critical Analysis of Pertinent Legislation Regulating Genetic Modification in Food and Agriculture in South Africa at 20 unpublished paper.

²⁴² Preamble, GMO Act.

²⁴³ Section 2.1. (a) GMO Act. Section 1 defines genetically Modified Organisms to mean organisms the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and genetic modification shall have a corresponding meaning.

²⁴⁴ Section 2.2. (1) GMO Act. Section 1 defines gene therapy to mean a technique for delivering functional genes (to replace aberrant ones) into living cells by means of a genetically modified vector or by physical means in order to genetically alter the living cells.

²⁴⁵ Established under sections 3, 10 and 8 of the GMO Act respectively.

²⁴⁶ Section 5 GMO Act.

²⁴⁷ Section 11 GMO Act.

²⁴⁸ Section 9 (a) GMO Act.

²⁴⁹ Section 15 and 16 GMO Act.

²⁵⁰ Section 17 GMO Act.

²⁵¹ Section 21 GMO Act.

recommendation of the Council.²⁵² A right of appeal is reserved for parties who are aggrieved by the decisions of the Council.²⁵³ The Act provides for confidentiality relating to information contained in applications.²⁵⁴ The Act also provides for the enactment of Regulations under section 20. The primary focus of the GMO Act appears to be the establishment of regulatory bodies and the permitting regime is left to the regulations.²⁵⁵

4.2.2 The GMO Regulations

Regulations have been enacted under section 20 of the GMO Act. They came into operation on 1 December 1999. The Regulations establish a permitting regime in terms of which various activities, including the use and release of GMOs may not be carried out without a permit.²⁵⁶ The application procedure is prescribed.²⁵⁷ Facilities engaged in GMO related activities must be registered and maintain their records.²⁵⁸

A Risk assessment is required before any activities involving genetic modification may be carried out.²⁵⁹ A procedure for public notification of intended releases of GMOs is prescribed.²⁶⁰ Measures to be taken in the case of accidents are set out²⁶¹ as are provisions for effective waste management.²⁶² Finally, the Regulations prescribe detailed procedures for appeals lodged under the Act.²⁶³

4.2.3 The Genetically Modified Organisms Amendment Bill

South Africa acceded to the Biosafety Protocol on 14 August 2003.²⁶⁴ Following the coming into force of the Biosafety Protocol in November 2003, amendments to the GMO

²⁵² Section 14 GMO Act.

²⁵³ Section 19 GMO Act.

²⁵⁴ Section 18 GMO Act.

²⁵⁵ Eastwood J, 'GMO Amendment Bill- Perpetuating the Shortcomings of the GMO Act.' Unpublished paper at 3.

²⁵⁶ Regulation 2 GMO Regulations.

²⁵⁷ Regulation 5 GMO Regulations.

²⁵⁸ Regulation 4 GMO Regulations.

²⁵⁹ Regulation 3 GMO Regulations.

²⁶⁰ Regulation 6 GMO Regulations.

²⁶¹ Regulation 7 GMO Regulations.

²⁶² Regulation 8 GMO Regulations.

²⁶³ Regulation 9 GMO Regulations.

²⁶⁴ <http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=df>.

Act were proposed in order to bring it in line with the Protocol.²⁶⁵ This process culminated in the publication of the GMO Amendment Bill.²⁶⁶

The purpose of the GMO Amendment Bill is set forth in its Preamble. It seeks among others to revise certain definitions and incorporate new ones. The definition of ‘accident’ is revised by removing from it certain phrases and replacing these with alternative phrases.²⁶⁷ In addition, an alternative definition for accident is provided.²⁶⁸ New definitions that the Bill incorporates include; activity,²⁶⁹ biosafety,²⁷⁰ Biosafety Clearing House²⁷¹ and environmental impact assessment.²⁷² The Bill also seeks to amend the provisions concerning institutions. Accordingly, the composition, remuneration, powers, and functions of the various institutions are amended.²⁷³ Procedures relating to application for and issuance of permits are explained under the Bill.²⁷⁴ The GMO Amendment Bill makes provision for risk assessment and liability.²⁷⁵ It amends the confidentiality clause and the offence and penalty provisions.²⁷⁶ Finally, the Bill makes provision for procedures under the appeal process.²⁷⁷ Although the GMO Amendment Bill seeks to amend a wide range of issues under the GMO Act, it however, does not adequately address those issues and the amendments are generally made in a piece meal manner.²⁷⁸ A critique of relevant provisions of the Amendment Bill will be included in the critique that follows in chapter 5.

²⁶⁵ Eastwood, *supra* note 255 at 3.

²⁶⁶ *Ibid.*

²⁶⁷ Section 1 (a) i GMO Amendment Bill that amends section 1 of the GMO Act.

²⁶⁸ Section 1 (a) ii GMO Amendment Bill.

²⁶⁹ Section 1 (b) GMO Amendment Bill

²⁷⁰ Section 1 (c) GMO Amendment Bill.

²⁷¹ Section 1 (d) GMO Amendment Bill.

²⁷² Section 1 (h) GMO Amendment Bill.

²⁷³ Sections 2-9 GMO Amendment Bill that amends sections 3-12 of the GMO Act.

²⁷⁴ Section 14 GMO Amendment Bill that amends section 20 of the GMO Act.

²⁷⁵ Section 11 GMO Amendment Bill that amends section 17 of the GMO Act.

²⁷⁶ Section 12 and 15 GMO Amendment Bill that amends sections 21 of the GMO Act respectively.

²⁷⁷ Section 13 GMO Amendment Bill that amends section 19 GMO Act.

²⁷⁸ Mayet M, ‘Comments on the Genetically Modified Organisms Amendment Bill (revised version), 2005 at 3 Unpublished paper.

4.3 The Policy documents

4.3.1 Biosafety Policy

In August of 2005, a Draft Biosafety Policy²⁷⁹ was published. The Biosafety Policy applies to current and future applications of GMOs including contained use, controlled and uncontrolled release in agriculture, human and veterinary medicine.²⁸⁰ The Biosafety Policy will facilitate the establishment of safeguards, vital for maximizing the benefits while minimizing the risks of biotechnology.²⁸¹ The Policy will promote sustainable development through providing mechanisms for the safe use of biotechnology.²⁸² The Policy acknowledges the potential risks of biotechnology to human and animal health and the environment. It also states key factors to be taken into account in biosafety such as socio-economics, public awareness, education, participation and access to information.

The Biosafety Policy seeks to set up uniform measures and requirements for risk assessment, EIA and assessments of socio-economic impact.²⁸³ In addition, it seeks to promote and facilitate access to information in biosafety regulation.²⁸⁴ The Biosafety Policy is important as it sets forth the aspirations of South Africa and the course that it wishes to take in the context of biosafety regulation. Consequently, national legislation relating to biosafety should reflect the ideals that are set out in the Biosafety Policy.

4.3.2 Guideline Document for use by the Advisory Committee.

These Guidelines²⁸⁵ (Advisory Committee) were established in accordance with section 5 of the GMO Act, which calls for the development, and publication of guidelines for all uses of GMOs.²⁸⁶ The Guidelines aim to do the following; provide general additional information on the GMO Act provisions; the institutions created there under and the

²⁷⁹ Department of Agriculture Publication of Draft Biosafety Policy for Comments GN 1576/2005 in GG 27913 dated 26 August 2005.

²⁸⁰ Ibid.

²⁸¹ Ibid.

²⁸² Ibid.

²⁸³ Ibid.

²⁸⁴ Ibid.

²⁸⁵ GN 1047/2004 in GG 26422 dated 11 June 2004.

²⁸⁶ Section 5 (l) GMO Act.

application process for permits.²⁸⁷ The Guidelines provide for among others, procedure for risk identification and process for risk assessment, for a fast tracking mechanism and for granting of authorizations.²⁸⁸

4.3.3 Guideline Documents for Work with Genetically Modified Organisms

This Guidelines²⁸⁹ document herein after (General Guidelines) were similarly enacted under section 5 of the GMO Act. They are also meant to provide general information on the provisions of the Act, on the functioning of its institutions and the application process for permits.²⁹⁰ The General Guidelines are meant to complement the GMO Regulations. The responsibilities of applicants/permit holders and farmers/companies engaged in GMO activities are set out in these Guidelines.²⁹¹ They also set out potential adverse effect resulting from GMO activities, and provide information on risk assessment and risk management procedures.²⁹²

4.4 Other Relevant Legislation

4.4.1 The Constitution of the Republic of South Africa Act

The Constitution is the supreme law of the land and any other law that is inconsistent with it is invalid.²⁹³ The Constitution is relevant to the question of biosafety regulation in at least three different ways. Firstly, it enshrines the environmental human right in its Bill of Rights. It states:

Everyone has the right to (a) an environment that is not harmful to their health or well-being; and (b) to have the environment protected, for the benefit of the present and future generations, through reasonable legislative and other measures ...²⁹⁴

²⁸⁷ See foreword by Minister at 115 of Guidelines (Advisory Committee).

²⁸⁸ See part 7 and 8, 9 and 10 respectively of the Guidelines (Advisory Committee).

²⁸⁹ GN 1046/2004 in GG 26422 dated 11 June 2004.

²⁹⁰ See foreword by Minister at 47 Guidelines (General).

²⁹¹ See part 2 of the Guidelines (General).

²⁹² See part 3, 5 and 7 of the Guidelines (General).

²⁹³ Section 2 of the Constitution.

²⁹⁴ Section 24 of the Constitution.

The inclusion of the environmental right is significant in that all the environmental related laws must be consistent with this right. Further, the GMO Act and their Regulations as amended²⁹⁵ may be argued to be legislative measures by the government to protect the environment from harm resulting from release of GMOs into the environment, which could potentially affect the human health.

Secondly, the Constitution prescribes the right of access to information.²⁹⁶ It guarantees access to information held by the state and any other person where such information is required for the protection of any other rights such as the environmental right.²⁹⁷ The GMO Act has to be consistent with the constitutional provision on access to information particularly because activities such as the release of GMOs into the environment have the potential to infringe on the environmental right. The GMO Act unfortunately is inconsistent with the Constitution as will be discussed in the critique that follows in chapter five.

Thirdly, the Constitution guarantees the right to just administrative action.²⁹⁸ Administrative action must be lawful, reasonable and procedurally fair.²⁹⁹ In addition, persons whose rights have been adversely affected by administrative action are entitled to written reasons.³⁰⁰ The GMO Act must be consistent with these constitutional provisions, as the Constitution is the supreme law. More so, as decisions made by the institutions under the GMO Act constitute administrative action.³⁰¹ The GMO Act is not entirely consistent with the constitutional provisions on just administrative action. Details of its inconsistency will be discussed in the critique that follows in chapter five.

²⁹⁵ Including the GMO Amendment Bill.

²⁹⁶ Section 32 of the Constitution.

²⁹⁷ Section 32.1 (a) and (b), the Constitution.

²⁹⁸ Section 33 of the Constitution.

²⁹⁹ Section 33.1 of the Constitution.

³⁰⁰ Section 33.2 of the Constitution.

³⁰¹ Section of 1(a) ii PAJA, *supra* note 231. Administrative action includes any action taken by an organ of state exercising powers under any legislation.

4.4.2 Promotion of Access to Information Act

The Constitutional right of access to information is given effect through the Promotion of Access to Information Act (PAIA).³⁰² A party seeking to access information held by the state or a private citizen may apply to court where such information is needed to protect or enforce their rights; such as the environmental right. For biosafety purposes, the provisions of the PAIA may be invoked for instance, where parties interested in the public participation process require information to enable them make comments on a proposed activity. The *Biowatch case*³⁰³ Biowatch an NGO obtained a court order compelling the Registrar of GMOs to make available certain information pertaining to the commercial release of GMOs. Although the case was not brought under the provisions of PAIA, as it was not yet in force, it would have been appropriate to invoke its provisions had it been operational. PAIA makes provision for grounds for refusal of access.³⁰⁴ However, it also sets out grounds for mandatory disclosure, which trumps the refusal provisions.³⁰⁵

4.4.3 Promotion of Administrative Justice Act

The Promotion of Administrative Justice Act (PAJA) seeks to give effect to the Constitutional right to just administrative action.³⁰⁶ Just administrative action must be lawful, reasonable, and procedurally fair and include a right to written reasons for administrative action.³⁰⁷

PAJA also makes provision for judicial review where it details the grounds, procedure and the remedies for judicial review.³⁰⁸ The PAJA is a very important tool especially in the context of permitting of GMOs. Persons aggrieved by decisions granting or denying permits for GMO related activities, may rely on its provisions and seek recourse from the

³⁰² Long title and Section 9 PAIA, supra note 231. PAIA operates along side *the Promotion of Access to Information Act, 2000 Regulations regarding the Promotion of Access to Information*, No. R. 187 dated 17 February 2002.

³⁰³ *Biowatch Trust V the Registrar Genetic Resources and Others* 2005 (4) 111 T.

³⁰⁴ Section 33 PAIA.

³⁰⁵ Section 46 PAIA.

³⁰⁶ Long title, PAJA.

³⁰⁷ Ibid.

³⁰⁸ Sections 6, 7 and 8 PAJA.

courts. Similarly, institutions created under the GMO Act are enjoined to ensure that they comply with the provisions of the PAJA in making decisions under the Act. Thus, the relevance of the PAJA may be viewed as two fold. For persons seeking to engage in GMO related activities, the provisions of the PAJA are relevant in seeking redress where they have been aggrieved by administrative decisions such as a refusal to grant permits. On the other hand, persons opposing the granting of permits may invoke the provisions of the PAJA where they have not received fair administrative action.

4.4.4 The National Environmental Management Act

The National Environmental Management Act (NEMA) is the principal framework legislation for environmental protection in South Africa, which gives effect to 24 of the Constitution. The Act contains a number of crucial tools that could be used to enhance environmental protection relating to GMOs.³⁰⁹

NEMA prescribes a set of principles which all organs of state whose actions ‘may significantly’ affect the environment must apply.³¹⁰ The regulatory bodies established under the GMO Act, such as the Executive Council, are therefore bound to consider these principles when exercising their functions and making decisions under the Act. It is currently uncertain whether these principles are being taken into account by the relevant authorities.³¹¹ Notable principles include; the principle of sustainable development;³¹² public participation in environmental governance;³¹³ precautionary principle;³¹⁴ preventative principle³¹⁵ and the polluter pays principle.³¹⁶

NEMA requires that the potential impact of certain listed activities on the environment must be investigated and assessed before any authorization is granted for them to take

³⁰⁹ Mayet M. ‘Analysis of South Africa’s GMO Act of 1997’ unpublished paper written for Biowatch South Africa, 2000 at 5.

³¹⁰ Section 2 NEMA.

³¹¹ Mayet, *supra* note 241 at 45.

³¹² Section 2.3 NEMA.

³¹³ Section 2.4 (f) NEMA.

³¹⁴ Section 2.4 vii NEMA.

³¹⁵ Section 2.4.1 (a) i, iii and viii NEMA.

³¹⁶ Section 2.4 (p) NEMA.

place.³¹⁷ An environmental impact assessment (EIA) is a tool that is used in decision-making.³¹⁸ A list of activities identified in terms of section 24 of NEMA³¹⁹ lays down activities that may not be undertaken without EIAs. The release of GMOs into the environment is one such ‘listed activity’.³²⁰ The inclusion of the release of GMOs under the listed activities is crucial since the GMO Act does not provide for mandatory EIAs and risk assessment.³²¹ These provisions may be relied upon to demand for mandatory EIAs preceding release of GMOs into the environment.

NEMA’s duty of care provisions are also of potential relevance.³²² Any form of damage resulting from GMO related activities may trigger these provisions, which impose liability on the person causing the damage.³²³

NEMA prescribes what form of ‘reasonable measures’ must be taken by persons responsible for causing ‘significant pollution’ or degradation of the environment.³²⁴ Although the Act does not define ‘significant pollution’, it defines pollution as follows:

‘pollution means any change in the environment caused by substances, radioactive or other waves or noise, odours, dust or heat, emitted from any activity, including the storage or treatment of waste or substances, construction and the provision of services, whether engaged in by any person or organ of state, where that change has adverse effects on human health or well being or on the composition, resilience and the productivity of natural or managed ecosystems, or on material useful to people, or will have such effect in the future.’³²⁵

Pollution is very broadly defined and this could include the slightest change in conditions. This provision could arguably encompass damage caused by GMOs especially since the

³¹⁷ Section 24.1 NEMA.

³¹⁸ More on EIA in Glazewski *supra* note 71 at 227-252.

³¹⁹ List of Activities and Competent Authorities identified in Terms of Section 24 and 24D of the National Environmental Management Act, 1998. GNR 386 published in GG 28753 of 21 April 2006.

³²⁰ Activity 21, *Ibid*.

³²¹ Barron, *supra* note 25.

³²² Section 28 NEMA.

³²³ Mayet, *supra* note 241 at 48.

³²⁴ Section 28.3 NEMA.

³²⁵ Section 1 NEMA.

courts have considered the threshold in ‘significant’ as low.³²⁶ Reasonable measures envisaged under NEMA include containing or preventing the movement of the pollutant or the cause of the degradation and eliminating the source of the pollution.³²⁷ In case of a pollution incident resulting from GMOs, responsible persons may be compelled to take reasonable measures relying on these provisions.

NEMA’s emergency incidents provisions may also be relevant in the GMO context.³²⁸ An ‘emergency incident’ is defined to mean an ‘...unexpected sudden occurrence that may cause serious danger to the public or potentially serious pollution or detriment to the environment’.³²⁹ NEMA obliges persons responsible for such incidents to not only report but also take reasonable measures to contain the situation.³³⁰ The escape of GMOs from a laboratory causing detrimental effects to the environment may be classified under ‘emergency incidents’. In such circumstances, these provisions may be relied upon to compel responsible persons to take reasonable measures.

Access to information is provided for in NEMA.³³¹ This provision enables every person to have access to information held by the state or its organs affecting the environment. This provision would be useful for purposes of accessing information especially in the absence of similar provisions in the GMO Act.

Section 32 provides for legal standing in environmental litigation. It empowers persons to bring action under NEMA and any other law in the interest of environmental protection. Since GMO related activities pose environmental risks, these provisions may be applied to institute action in that regard.

³²⁶ *Hichange Investments (Pty) Ltd v Cape Produce Company (Pty) Ltd t/a Pelts Products and Others 2004 (2) SA 393 (ECD)*.

³²⁷ Section 28.3 (d) and (e) NEMA.

³²⁸ Section 30 NEMA.

³²⁹ Section 30.1 NEMA.

³³⁰ Section 30.3 and 4 NEMA.

³³¹ Section 31 NEMA.

4.4.5 The Foodstuffs, Cosmetics and Disinfectants Act

The Foodstuffs, Cosmetics and Disinfectants Act (FCDA), regulates the safety of all foodstuffs in South Africa and this includes foodstuffs derived from GMOs.³³² This Act is relevant in light of the fact that it provides for safety assessment of foodstuffs including products of GMOs. Particularly so because imported food which contains products of GMOs or processed GM foods fall outside the scope of the GMO Act.³³³ The GMO Act contains no food safety provisions.

In January 2004, Regulations on the labeling of foodstuffs derived from certain techniques of genetic modification were published.³³⁴ The Regulations make provision for mandatory and voluntary labeling of foodstuff acquired through certain techniques of genetic modification requiring mandatory labeling.³³⁵

4.4.6 The National Environmental Management Biodiversity Act

The National Environmental Management Biodiversity Act (NEMBA) reforms all laws of South Africa regulating Biodiversity.³³⁶ Its objectives include; providing for the management and conservation of biological diversity; giving effect to international agreements relating to biodiversity; and establishing the South African National Biodiversity Institute (SANBI) among others.³³⁷ The Department of Agriculture must in accordance with NEMBA, through the implementation of the GMO Act manage, conserve and sustain South Africa's Biodiversity.³³⁸ SANBI is charged with the duty to monitor and report to the Minister the impacts of GMOs that have been released into the environment.³³⁹

³³² The Draft Biosafety Policy, GN 1576/2005 published 26 August 2006 at 11

³³³ Mayet, *supra* note 309 at 4.

³³⁴ *Regulations relating to the Labelling of foodstuffs obtained through certain Techniques of Genetic Modification* GNR 25 in GG 25908 dated 16 January 2004.

³³⁵ *Ibid.*

³³⁶ Glazewski, *supra* note 71 at 268.

³³⁷ Preamble and Section 2 NEMBA.

³³⁸ Biosafety Policy.

³³⁹ Section 11.1 (b) NEMBA.

NEMBA defines alien species to mean ‘a species that is not indigenous species’.³⁴⁰ Alien species may arguably include GMOs as these are not indigenous to the environment in which they are released. Therefore, NEMBA’s provisions on alien species may arguably apply to GMOs.³⁴¹ Alien species may not be introduced into new ecosystems without authorization.³⁴² In addition, restricted activities involving aliens may not be carried out without a permit.³⁴³ Furthermore, NEMBA refers to the GMO Act under its invasive species provisions.³⁴⁴ An invasive specie ‘means any specie whose establishment and spread outside of its natural distribution range may result in environmental harm or harm to health’.³⁴⁵ The Minister for National Environmental Management may deny the grant of permit under the GMO Act if they believe that such grant will pose a threat to the environment or indigenous species.³⁴⁶ As should be evident from the above overview, South Africa’s legal regime of relevance to biosafety regulation is rather fragmented and inadequate in various respects. The strengths and weaknesses of the current regime are discussed below.

³⁴⁰ Section 1.1 (a) NEMBA.

³⁴¹ Sections 65-69 NEMBA.

³⁴² Section 64.1 (a) NEMBA.

³⁴³ Section 65.1 NEMBA.

³⁴⁴ Section 78 NEMBA.

³⁴⁵ Section 1.1 NEMBA.

³⁴⁶ Section 78.1 NEMBA.

CHAPTER 5

CRITIQUE OF SOUTH AFRICA'S BIOSAFETY REGIME

5.1 Objectives and Scope of the GMO Act

The objectives of the GMO Act are incorporated within its preamble. Notable among the objectives is the reference to 'promote the responsible development, production, use and application of GMOs'. This provision is regarded as unsatisfactory as law, which is meant to regulate the technology, should not be the same one promoting it.³⁴⁷ The preamble to the GMO Act gives the distinct impression that the law is biased towards promoting the technology while the objective of biosafety regulation should arguably be to ensure protection or safety in the application of biotechnology.³⁴⁸

The GMO Act has a narrow scope of application, which excludes products of GMOs.³⁴⁹ The Act applies to the following activities; genetic modification of organisms; development, production, release, use and application of genetically modified organisms; and the use of gene therapy.³⁵⁰ Mayet notes that the reference to genetic modification envisages only the process of genetic modification. There is no reference whatsoever to GMO products thereby excluding them from the ambit of the Act. Foodstuffs derived from GMOs, such as corn and soya may pose a danger to the environment even after having gone through the intestinal tracts of humans and animals.³⁵¹ These products should therefore be subject to regulation. The objectives and scope of the GMO Act appear to be inadequate in that respect.

5.2 Institutional Arrangements

As is previously mentioned, the GMO Act establishes regulatory institutions such as the Executive Council, the Registrar and the Advisory Committee.³⁵² A number of crucial

³⁴⁷ Mayet, *supra* note 241 at 20.

³⁴⁸ Article 1 Biosafety Protocol.

³⁴⁹ Mayet, *supra* note 241 at 21.

³⁵⁰ Section 2.1 (a), (b) and (c). GMO Act.

³⁵¹ Mayet, *supra* note 241 at 2.

³⁵² Sections 3, 8, and 10 of the GMO Act.

issues arise concerning these regulatory bodies such as their powers and functions; - the discretionary nature of these powers and functions; and their composition.

Firstly, it is noted that the Minister of Agriculture has unfettered discretion over the composition of these bodies, which potentially undermines their independence.³⁵³ In addition, civil society is unrepresented on such bodies as the advisory committee which comprises predominantly of members from the scientific community.³⁵⁴ This is regrettable because GMOs require a multidisciplinary approach to ensure that that evaluation of potential risks is done from a broader perspective.³⁵⁵ These institutions should ideally include broad ranging membership such as sociologists, environmentalists and scientists.³⁵⁶

The Council is given lots of powers and discretion without any apparent obligations in performing their duties.³⁵⁷ The Amendment Bill appears to exacerbate the state of things by giving more power to the Registrar under section 6 of the Amendment Bill.³⁵⁸ Mayet points out that given that the entire co-ordination of the biosafety regulatory system will depend on the Registrar there ought to be some checks and balances, which are currently absent.

On positive note however, the Amendment Bill grants the Council very important powers with respect to issuing of permits; the power to reconsider decisions that have been taken with respect to issuing of permits.³⁵⁹ This power to review decisions is vital as new information can be taken into consideration subsequent to the initial grant of a permit.³⁶⁰

³⁵³ Rohlwink I, 'A Critical Analysis of the Genetically Modified Organisms Bill: Does it Remedy the Inadequacies of the Current Regime?' Unpublished LLB Dissertation. 2006 at 25.

³⁵⁴ Mayet, *supra* note 241 at 22.

³⁵⁵ *Ibid.*

³⁵⁶ *Ibid.*

³⁵⁷ Section 5 GMO Act.

³⁵⁸ Mayet, *supra* note 278 at 9.

³⁵⁹ Eastwood, *supra* note 255 at 13.

³⁶⁰ *Ibid.*

5.3 Risk Assessment

It is internationally acknowledged that authorizing GMO related activities should be done on a precautionary basis.³⁶¹ GMOs are a relatively new area and there is not a lot of certainty about the extent of risks they pose. This is attributed to the novelty of GMO technology.³⁶²

The GMO Act and its Regulations do not adequately provide for risk assessment. First, the GMO Act fails to prescribe specific mandatory principles for risk assessment. Rather, it relies on the use of the voluntary guidelines, which are non-binding in nature.³⁶³ Secondly, risk assessments and environmental impact assessments are not mandatory in terms of the GMO Act.³⁶⁴ The Council ‘may’ require an applicant for a permit to submit as assessment of risks and ‘where required’ an assessment of the impacts on the environment.³⁶⁵ The language of the provision appears to grant the Council the discretion to determine when a risk assessment and environmental impact assessment will be required. Regulation 3 (1), which on the face of it appears to require the Council to consider the risks and environmental impacts before making decisions regarding the grant of permits, only applies to ‘genetic modification’.³⁶⁶ Although ‘genetic modification’ is not defined in the GMO Act, it does not appear to include activities such as the release of GMOs into the environment.³⁶⁷

The recent EIA Regulations³⁶⁸ promulgated under section 24 of the NEMA list the release of genetically modified organism into the environment as one of the activities requiring an EIA before authorisation. NEMA’s EIA Regulations, which on the face of it appear to redress the situation, do not actually do so as they only require mandatory EIA where the release of GMOs into the environment is required by the GMO Act.³⁶⁹ This position is rather absurd, as the GMO Act does not require mandatory EIA prior to the

³⁶¹ Barron, *supra* note 25 at 108.

³⁶² *Ibid.*

³⁶³ Mayet, *supra* note 309 at 3.

³⁶⁴ Barron, *supra* note 25 at 109.

³⁶⁵ As set out in section 5 (a) and 5 (g) of GMO Act.

³⁶⁶ Barron, *supra* note 25 at 110.

³⁶⁷ *Ibid.*

³⁶⁸ NEMA EIA Regulations GNR 386 published in GG 28753 21 April 2006.

³⁶⁹ Activity 21. *Ibid.*

release of GMOs. It is the environmental impact resulting from the release of GMOs into the environment that raises concerns, which should ideally be investigated before authorization and not genetic modification *per se*.³⁷⁰

The Amendment Bill one of whose objectives is to provide for risk assessment determinations does not adequately address the issue of risk assessment. It unfortunately introduces the 'WTO language' to be applied in risk assessment by reference to 'scientifically based assessment'.³⁷¹ The introduction of this concept is particularly worrying because it potentially excludes socio-economic considerations from the risk assessment process.³⁷²

The Biosafety Protocol specifically refers to socio economic considerations that parties may take into account when carrying out risk assessments.³⁷³ One socio-economic consideration envisaged in that regard is the value of biological diversity to local and indigenous communities.³⁷⁴

The GMO Act, the Regulations and the Guidelines do not refer to these considerations. The Amendment Bill refers to socio-economic considerations in very ambiguous terms.³⁷⁵ It appears to make a distinction between the scientific-based risk assessment, environmental impact assessment and socio-economic considerations. It is submitted that the position should rather be one that integrates socio-economic considerations in risk assessment and environmental impact assessment.

³⁷⁰ Barron, *supra* note 25 at 110-111.

³⁷¹ Mayet, *supra* 280 at 6. See also section 12 Amendment Bill that amends section 18 GMO Act.

³⁷² Eastwood, *supra* note 255 at 15.

³⁷³ Article 26 Biosafety Protocol.

³⁷⁴ Biosafety Guide, *supra* note 39.

³⁷⁵ Section 14 of the Amendment Bill, the proposed amendment to section 20 of the GMO Act.

5.4 Liability Regime

Liability regimes are fairly common today and they include damage caused by GMOs to the environment.³⁷⁶ Liability regimes are intended to provide a remedy in instances where damage occurs.³⁷⁷ Commenting on the liability provision in the GMO Act, Mayet states that they are ‘astonishing’. The Act attempts to protect the developers of GMOs from liability by imposing liability on ‘end-users’ and consumers.³⁷⁸

As noted by Eastwood, this is a very unfair situation as users, such as consumers, may not even be aware that they are dealing with GMOs considering that there are no labelling requirements in the GMO Act.³⁷⁹ This is inconsistent with the basic tenets of fairness, equity and the ‘polluter pays’ principle entrenched in NEMA.³⁸⁰ According to the ‘polluter pays’ principle, the person responsible for the damage such as the initial developer of the products, should be responsible for remediation.

The liability provisions in the GMO Act are further inadequate in many respects. The Act does not set out the scope of the damage envisaged³⁸¹ it rather prescribes quite ambiguously, that users have to ensure that appropriate measures are taken to avoid adverse effect on the environment.³⁸² Clearly, the Act refers only to damage to the environment that should be taken into account. This is rather unacceptable given that GMOs will, in addition most frequently affect human and animal health.

It is argued that in addition, the GMO Act fails to deal with the standard of liability, that is to say whether it is strict liability, fault based or a combination of both.³⁸³ The questions of redress is inadequately addressed in that there is no indication of what measures are to be taken for mitigation, control or containment despite the fact that these

³⁷⁶ Feris, supra note 227 at 1/26.

³⁷⁷ Ibid.

³⁷⁸ Mayet, supra note 309 at 3. See section 17.2 GMO Act. A user is defined in section 1 of the GMO Act to ‘mean any natural or legal person or institution responsible for the use of genetically modified organisms and includes an end-user or consumer.’

³⁷⁹ Eastwood, supra note 255 at 10.

³⁸⁰ Mayet, supra note 309 at 3.

³⁸¹ Feris, supra note 227 at 12/26.

³⁸² Section 17.1 GMO Act.

³⁸³ Ibid.

are basic requirements for redress regimes.³⁸⁴ Furthermore, the Act does not make provision for insurance or financial security, which would cover liability for environmental damage.³⁸⁵

As noted earlier,³⁸⁶ NEMA provisions on duty of care and emergency incidents are relevant to the GMOs particularly in the context of damage resulting from their use and release. These provisions place liability on persons responsible for the damage and these may include the producer of a GMO, hence, providing an arguably more just liability regime. Although the NEMA provisions are welcome, it would be preferable to have such provisions included in the GMO Act, and not in a different piece of legislation. It is noted with merit that the Amendment Bill attempts to improve on the liability regime where it makes small amendments. The Bill appears to extend the scope of damage from the environment to human and animal health.³⁸⁷ This is undoubtedly very important because ultimately the concern is for safety of human beings.

5.5 Decision-making

With respect to decision-making, the GMO Act is inadequate in a number of ways. First, the Act fails to make provision for guidance in decision-making.³⁸⁸ This is apparent in its failure to adopt guidelines on the application of the precautionary principle, risk assessments, environmental impact assessments as well as socio-economic impact assessments.³⁸⁹

The precautionary principle, endorsed by the Biosafety Protocol in the context of biosafety, is ‘bastardised’ under the GMO Act.³⁹⁰ The GMO Act provides that:

³⁸⁴ Ibid.

³⁸⁵ Ibid.

³⁸⁶ Section 4.2.1 See section 28 and 30 of NEMA.

³⁸⁷ Section 11(a) 1 of the Bill that amends section 17 of the GMO Act.

³⁸⁸ Eastwood, *supra* note 255 at 8.

³⁸⁹ Ibid.

³⁹⁰ Mayet, *supra* note 309 at 3.

‘Lack of scientific knowledge or consensus on the use of genetically modified organisms shall not be interpreted as indicating a particular level of risk, an acceptable risk or absence of risk.’³⁹¹

This provision effectively renders its application nugatory as lack of scientific knowledge or consensus on the safe use of GMOs is deemed irrelevant and will not be taken into account in decision-making.³⁹² This position is rather contradictory on the part of the Government because the National Environmental Management Policy expressly states that ‘Government will apply a risk averse and cautious approach.’³⁹³

The Amendment Bill does not adequately address the issues surrounding decision-making, which remains problematic and excludes the Biosafety Protocol’s precautionary principle.³⁹⁴ As noted earlier, the Amendment Bill unfortunately rather introduces the WTO terminology of ‘science based risk assessment’.³⁹⁵ As noted previously, the GMO Act fails to prescribe mandatory requirements for important decision-making tools such as EIAs, risk assessments and socio-economic impact assessments. This further compounds the issue of decision-making.

5.6 Public Participation

The GMO Act does not make adequate provision for public participation. Public participation is scarcely provided for under the Regulations. Applicants are required to notify the public of proposed releases of GMOs prior to their application for permits.³⁹⁶ The notice is to be published in a local newspaper in the area in which the proposed release is to take place.³⁹⁷ This is problematic as such notice would not be accessible to potential interested members of the public in other areas. Another problem relates to the contents of the notice to be published that are rather inadequate for the public to make any meaningful comments.³⁹⁸ Information such as risk assessments and EIAs would

³⁹¹ Regulation 3.2 GMO Regulations.

³⁹² Mayet, *supra* note 241 at 27.

³⁹³ Ibid 26. See section 2.4 (a) (vii) NEMA.

³⁹⁴ Mayet *supra* note 278 at 7.

³⁹⁵ Ibid.

³⁹⁶ Regulation 6.1 GMO Regulations.

³⁹⁷ Regulation 6.4 GMO Regulations.

³⁹⁸ Regulation 6.3 GMO Regulations.

particularly aid the public in making meaningful comments. The 30 days period within which the public is expected to respond is insufficient and impractical for any meaningful comments to be made. Worse still, the regulatory institutions such as the Advisory Committee exclude any kind of civil society participation.³⁹⁹ This is a serious shortcoming as it is inconsistent with the basic tenets of democracy and the principles of environmental governance.⁴⁰⁰ It is further inconsistent with the NEM principles, one of which expressly recognizes the importance of public participation.⁴⁰¹

Consequently, in instances where permits are not required, public participation does not take place. Since GMOs dealt with under 'contained use' are exempt from permit requirements, these activities take place without any form of public participation. It is argued by some commentators that the intention of the GMO Act appears to be to prevent the public from getting any information on the potential risks of GMOs to human and animal health, and the environment.⁴⁰² The provisions of PAJA overcome some these inadequacies.⁴⁰³ They make provision for adequate notice of the nature and purpose of a proposed administrative action, reasonable opportunity to make representations among others.

5.7 Labelling Requirements

Labelling of genetically modified foods is an important tool for providing information to the public and a mechanism that to manage risks.⁴⁰⁴ As an information tool, labelling sustains the consumer's right to know what he is purchasing or using. As a tool for risk management, users are able to get information from labels concerning the GMOs, GM's toxicity, allergen and environmental safety.⁴⁰⁵ Accordingly, end-users can use this information to take remedial measures to contain any risks pursuant to the information

³⁹⁹ Mayet, *supra* note 309.

⁴⁰⁰ *Ibid.*

⁴⁰¹ Section 2.4.f NEMA.

⁴⁰² Mayet, *supra* note 241 at 7.

⁴⁰³ See sections 3 and 4 PAJA.

⁴⁰⁴ Mayet M, 'Critical Analysis of South Africa's Labelling Regulations for Genetically Modified Food, Feed and Products Derived from GM-FED Animals. October 2004 <http://www.biosafetyafrica.net>

⁴⁰⁵ *Ibid.*

contained in the labels.⁴⁰⁶ Segregation is important especially during processing and storage as it prevents contamination of organic foods by GM foods.⁴⁰⁷

GMO products, such as foodstuffs, fall outside the ambit of the GMO Act. There is currently no mandatory labelling requirements for GM foods in South Africa whether locally produced or imported.⁴⁰⁸ There is also no requirement for segregating GM foods from non-GM foods.⁴⁰⁹ Food safety assessments are not included in the GMO Act. The underlying rationale for this appears to be that labeling and segregation are very expensive ventures which would lead to increased food prices and that is accordingly deemed unrealistic.⁴¹⁰

In the absence of labelling requirements and provisions on food safety in the GMO Act and its Regulations, the provisions of the FCD Act have to be invoked. The FDC Act is meant to safe guard consumers from harmful foodstuffs. The Act and its Regulations⁴¹¹ provide for the labeling of foodstuffs derived from certain techniques of genetic modification. Labelling is only required where the composition or the nutritional value of the food differs significantly from the characteristic composition of that foodstuff in its non-modified form.⁴¹² The Regulations define ‘significant difference’ to exist only where characteristics are different in terms of a scientific assessment of an appropriate analysis of data.⁴¹³ It is argued that this provision is altogether not realistic especially since it places the onus on consumers to ensure compliance.⁴¹⁴

⁴⁰⁶ Ibid.

⁴⁰⁷ Eastwood, *supra* note 255 at 11.

⁴⁰⁸ ‘Why Do We Need to Label Genetically Modified (GM) Food Products?’ Available at http://www.biosafetyafrica.net/briefing_papers.htm.

⁴⁰⁹ Ibid.

⁴¹⁰ According to the Department of Health, Ibid.

⁴¹¹ Regulations Relating to the Labelling of Foodstuffs Obtained through Certain Techniques of Genetic Modification GNR 25/GG 25908/16-01-2004.

⁴¹² Regulation 1, Ibid.

⁴¹³ Eastwood, *supra* note 255.

⁴¹⁴ Ibid at 11.

5.8 Confidentiality and Access to Information

The GMO Act contains provisions on confidentiality,⁴¹⁵ which arguably limit the constitutional right of access to information. The Act prescribes that applicants may request certain information be treated as confidential or undisclosed where they perceive it to be necessary. What is concerning is the fact that these provisions allow the Council to decide what kind of information should be kept confidential after consultation with the applicant.⁴¹⁶ This gives the Council a lot of discretion to determine what information to keep confidential, a discretion not guided by any guidelines. The Council having consulted with the applicant may withhold further information in the interest of protecting the applicants' intellectual property rights.⁴¹⁷ This appears to be an attempt to keep certain vital information about the potential risks of GMOs away from the public and clearly undermines the constitutional right of access to information.⁴¹⁸

The Amendment Bill fails to remedy the provisions on confidential information and access to information. Instead, it appears to narrow down the scope of information that may be disclosed. The description of the GMO is reduced to 'general' description.⁴¹⁹ Clearly, less information will be disclosed under a general description. In addition, the 'evaluation of foreseeable impacts' has been reduced to a 'summary of the 'scientifically based risk assessment'.⁴²⁰ The introduction of the latter concept will inevitably restrict access to information as other foreseeable impacts socio-economic for instance will not be included. The impact of all this will restrict the enjoyment of the right of access to information and consequently hamper public participation.⁴²¹ The NEMA provisions on access to information and the PAIA may however be applied to overcome restrictions on access to information.⁴²²

⁴¹⁵ Section 18 GMO Act.

⁴¹⁶ Section 18.2 GMO Act.

⁴¹⁷ Section 18.3. GMO Act.

⁴¹⁸ Mayet, *supra* note 241 at 25.

⁴¹⁹ Section 12(a) of the Amendment Bill, which amends section 18.2. (a).

⁴²⁰ Section 12 (b) of the Amendment Bill which amends section 18.2 (c).

⁴²¹ Mayet, *supra* 278 at 10.

⁴²² Section 31 NEMA and Section 46 PAIA.

5.9 Administrative Justice Provisions

The GMO Act and its Regulations contain provisions that are inconsistent with administrative justice provisions. The Constitution guarantees the right to administrative action that is lawful, reasonable and fair.⁴²³ PAJA further reaffirms this right. Although PAJA does not expressly define what amounts to a fair administrative process, it does charge an administrator to put into effect certain minimum guarantees for the benefit of the affected person. These include; adequate notice of the proposed administrative action; a reasonable opportunity to make representations; a clear statement of administrative action; adequate notice of right of review and adequate notice of the right to request reason.⁴²⁴ Under PAJA, ‘administrative action’ includes any decision taken in the exercise of public power.⁴²⁵ The authorization of permits under the GMO Act clearly constitutes administrative action.

The GMO Act and its Regulations are inconsistent with PAJA in various respects. First, they do not guarantee the right to reasons. Under the Act, this right is only available where an application has been turned down.⁴²⁶ It is submitted that reasons are still imperative even when a permit has been granted, as this will enable members of the public opposed to an approval to challenge the decision. However, the public could always fortunately make use of PAJA’s provisions to seek written reasons.⁴²⁷

Secondly, according to PAJA⁴²⁸ and its relevant regulations⁴²⁹ in order to give effect to the right to procedural fairness, an administrator must give the public notice of the nature and purpose of a proposed administrative action. The GMO Act and its regulations appear to fall short of these requirements.⁴³⁰ Neither the Council nor the Registrar is

⁴²³ Section 33 of the Constitution, Act 108 of 1996.

⁴²⁴ Section 3.2(b) PAJA.

⁴²⁵ Section 1.1 (a) ii PAJA.

⁴²⁶ Regulation 5.8 (b) GMO Regulations.

⁴²⁷ Section 5.1 PAJA.

⁴²⁸ Section 3.2 PAJA.

⁴²⁹ GN R 1022 in Government Gazette 23674 of July 2002.

⁴³⁰ Eastwood, *supra* note 255 at 5.

obliged to ensure that the public is given prior notice of decisions on issue, withdrawal or amendment of permits.⁴³¹

Regulation 6 of the GMO Regulations, which appears to address the issue of notification, is inadequate as it only relates to the release of GMOs and no other activities for which permits are granted.⁴³² Although PAJA calls for a ‘reasonable notice’ to be given such that the public can make meaningful comments,⁴³³ regulation 6 of the GMO Regulations provides a comment period of only 30 days, a period that is generally considered insufficient. In the *Biowatch case*,⁴³⁴ the High Court held the view that the notice reflected under regulation 6(3) is inadequate for purpose of informing the public and especially for the public to make informed decisions that would contribute to public debate.⁴³⁵

5.10 Appeals

The GMO Act and its Regulations do make provision for appeals.⁴³⁶ One of the shortcomings of the appeal provisions is the reference to ‘appellant’ in the Regulations. This gives the impression that only applicants under the GMO Act would have recourse to appeal.⁴³⁷ This is clearly not the case since the Act expressly states that ‘any person’ who feels aggrieved by a decision, not just the applicants.⁴³⁸ Hence, even non-applicants who are aggrieved by the decisions of the Council may appeal.

A further concern with the appeals provision is the fact that there is no requirement for notification of the public when a decision has been made. This is problematic as onus lies on the public to establish when the appellant has been notified of the decision in order to lodge an appeal timeously.⁴³⁹ This problem is compounded by the fact that according to

⁴³¹ Ibid.

⁴³² Ibid at 6.

⁴³³ Section 3.2 (b) PAJA.

⁴³⁴ Hichange, supra note 326.

⁴³⁵ *Biowatch Trust V the Registrar Genetic Resources and Others 2005 (4) 111 T.*

⁴³⁶ Section 19 read with regulation 9.

⁴³⁷ Mayet, supra note 241 at 32.

⁴³⁸ Section 19.1 GMO Act.

⁴³⁹ Mayet, supra note 241 at 32.

the Regulations, the appeal must be lodged within 30 days of the decision and there is no provision for extension of such time.⁴⁴⁰

5.11 Fast Track Mechanism

This mechanism operates through the stewardship of the main administrative organ of the GMO Act, the Registrar. The Act empowers the Registrar to ‘fast track’ any application for an activity concerning GMOs for which a permit has previously been granted.⁴⁴¹ In practice, this means that where a permit has previously been granted for an import of a particular GMO, GM maize for instance, subsequent imports of that maize may be approved without further risk assessments being done.

The fast track mechanism is problematic in that it gives the Registrar too much discretion to determine whether to request a further risk assessment. The result is that risk assessments may be by-passed if the Registrar deems this appropriate. It is submitted that further risk assessments may reveal new impacts and so the idea of the ‘fast track’ mechanism is altogether deplorable. Besides, a precautionary approach would not advocate such a mechanism given then there is so much uncertainty surrounding GMOs.

5.12 Enforcement and Compliance mechanisms

The GMO Act has very weak provisions on enforcement and compliance, which relies heavily on self-regulation.⁴⁴² There is no provision that calls for monitoring of compliance with permitting conditions.⁴⁴³ Permit holders are supposed to monitor their own compliance.⁴⁴⁴ There are provisions for inspectors who are supposed to carry out routine inspections on compliance with the Act and permit conditions.⁴⁴⁵ However, it is

⁴⁴⁰ Regulation 9.1 (a).

⁴⁴¹ Mayet, *supra* note 241 at 27.

⁴⁴² Eastwood, *supra* note 255 at 12.

⁴⁴³ *Ibid.*

⁴⁴⁴ *Ibid.*

⁴⁴⁵ Section 15 and 16. GMO Act.

said that these inspections are not done in a systematic manner, rather in a haphazard and erratic manner.⁴⁴⁶

In risk management, risks are identified and regulated with the sole purpose of reducing them.⁴⁴⁷ It is pertinent that all safety legislation provide for risk management measures that will ensure that monitoring of the activity continues even after the approval has been granted.⁴⁴⁸ The GMO Act does not make it the responsibility of the applicant to take any such measures.⁴⁴⁹ Neither is such measures provided for. The Amendment Bill does not attempt to remedy the situation. NEMA's duty of care provisions partly overcome this problem in that it prescribes reasonable measures that may be taken in case of pollution or degradation of the environment.⁴⁵⁰

Although the GMO Act has is criticized for its self-regulatory approach and the general inadequacies associated with its compliance and enforcement mechanism, the Amendment Bill tries to address certain of these inadequacies. The Bill empowers the Registrar to amend or withdraw a permit subject to instructions and conditions laid down by the Council.⁴⁵¹ This is very important because applicants, or the grantees of permits, will be motivated to work within the limits prescribed under the conditions. However, a problem remains with the fact that, the Council has the discretion to determine when to instruct the Registrar to amend or withdraw a permit.

5.13 Unintentional Release and Emergency Measures

GMOs are potentially hazardous substances. Therefore, it is preferable to have requisite measures and plans for when emergencies occur. The GMO Regulations attempt to provide for unintentional release and emergency measures although in a piecemeal fashion. The user is obligated to inform the Registrar both verbally and in writing should

⁴⁴⁶ Mayet, *supra* note 241 at 31.

⁴⁴⁷ *Ibid.*

⁴⁴⁸ *Ibid.*

⁴⁴⁹ *Ibid.*

⁴⁵⁰ Section 28.3 NEMA.

⁴⁵¹ Section 6 of the Amendment Bill which amends section 9.1 (c) of the GMO Act.

an accident involving GMOs occur.⁴⁵² An ‘accident’ is defined to mean ‘any incident involving an unintended general release of genetically modified organisms which could have an immediate or delayed impact on the environment’.⁴⁵³ The problem is that accidents are made entirely the responsibility of the user.⁴⁵⁴ The responsibility in case of accidents ought to be placed on the producers as well since they are more knowledgeable about GMOs.

These provisions are rather scanty and they do not indicate the type of measures that should be taken by the users. Similarly, no provision is made for public notification as such the public would not know when and what remedial measures to take in case of an emergency involving GMOs.⁴⁵⁵ NEMA’s provisions on control of emergencies may be applied in case of emergencies resulting from the use of GMOs as earlier noted.⁴⁵⁶ These are more comprehensive than the provisions set out in the Regulations.

5.14 Prohibition of Activities

The power to prohibit GMO related activities is acknowledged as a very crucial element of any biosafety regime. The GMO Act empowers the Minister to prohibit activities involving GMO on recommendation of the Council.⁴⁵⁷ What is lacking, however, is the power to prohibit certain GMOs, GM products or GM related activities. It is argued that such power is vital because some GMOs may display traits that are hazardous enough to justify imposing a ban on them.⁴⁵⁸

5.15 Inconsistency with Other Laws

There is enormous inconsistency and a lack of integration between the GMO Act and its Regulations, and other laws such as the PAJA, NEMA, PAIA and NEMBA as underlined earlier. NEMBA provides that, the Minister can deny the granting of a permit for a

⁴⁵² Regulation 7 GMO Regulation.

⁴⁵³ Section 1 GMO Act.

⁴⁵⁴ Regulation 7 GMO Regulations.

⁴⁵⁵ Mayet, supra note 241 at 30.

⁴⁵⁶ Section 4.4.4 of this work.

⁴⁵⁷ Section 14 GMO Act.

⁴⁵⁸ Mayet, supra note 241 at 31.

genetically modified organism, if in their opinion, the release of such organism into the environment will pose a threat to indigenous species or the environment unless a prior EIA has been conducted.⁴⁵⁹ The concern with this provision is that it appears to be impracticable as there is no mechanism to coordinate the NEMBA and the GMO Act.⁴⁶⁰ As such, it is doubtful whether the Council under the GMO Act gives the Minister an opportunity to exercise their discretion to deny granting of permits under the NEMBA.⁴⁶¹

The NEMA EIA regulations⁴⁶² list the release of genetically modified organisms as one of the activities that require screening before the issue of environmental authorization. However, this is applicable only where the GMO Act or the NEMBA requires assessment. What is startling is that, these two Acts do not contain the presumed assessment requirements.⁴⁶³

5.16 Conclusion

Biosafety regulation in South Africa is not a new phenomenon. In 1997, South Africa enacted its domestic biosafety legislation the GMO Act of 1997. This Act and its Regulations are very problematic to say the least and are generally inconsistent with standards prescribed in international instruments such as the Biosafety Protocol and the African Model Law. The inconsistency of the current regime with international standards may be attributed to the fact that its enactment preceded the prescription of these standards. However, what is noteworthy, is that, recent legislative amendments fail to remedy the current inconsistency. The Amendment Bill fails to remedy issues such as; the lack of a liability and redress regime; labeling; and the application of the precautionary principle. While the Biosafety Protocol is not clear on these issues, the African Model Law, attempts to provide comprehensive provisions that South Africa could have adopted. The South Africa's biosafety regime therefore, remains largely inadequate for biosafety purposes and inconsistent with international standards.

⁴⁵⁹ Section 78.1 NEMBA.

⁴⁶⁰ Eastwood, *supra* note 255 at 13.

⁴⁶¹ *Ibid.*

⁴⁶² NEMA EIA Regulations GNR 385-387 published in GG 28753 of April 2006. Regulation 21 list of activities.

⁴⁶³ Eastwood, *supra* note 255.

CHAPTER 6

AN OVERVIEW OF UGANDA'S BIOSAFETY REGIME

6.1 Introduction

The prescription of a biosafety regulatory framework for biosafety in Uganda is a recent phenomenon. According to Akol,⁴⁶⁴ the current Ugandan regime comprises the following; the National Biotechnology and Biosafety Policy;⁴⁶⁵ the National Biosafety Guidelines⁴⁶⁶ and the Draft Biosafety Regulations.⁴⁶⁷ Other relevant documents include the Manual on the Protection of Confidential Business Information in Uganda and the Manual on Transboundary Movement of GMOs in Uganda.

Like its East African counterparts, Uganda has an interim biosafety regulatory system.⁴⁶⁸ Although Uganda does not have an Act designated for biosafety regulation, the Government has drafted a Biosafety Bill. It is however yet to be enacted into law. The following discussion of Uganda's biosafety regulatory framework will focus mainly on the Draft Biosafety Regulations, which represents the current regime, and the Biosafety Bill, which represents the future regime. The Draft Biosafety Regulations and the Biosafety Bill will be analysed to determine whether they provide an adequate regime for protection of humans and the environment in the context of biosafety.

6.2 Principal Legislation

6.2.1 Draft National Biosafety Regulations

The Uganda National Council for Science and Technology (UNCST) is the competent authority for purposes of implementing the Biosafety Protocol.⁴⁶⁹ This institution, which

⁴⁶⁴ Akol D, Legal Frameworks for Liability and Redress for Biosafety in East Africa, available at http://www.ielrc.org/activities/workshop_0309/content/dako13_blank.pdf.

⁴⁶⁵ Uganda National Council for Science and Technology, (2003) National Biotechnology and Biosafety Policy, Republic of Uganda.

⁴⁶⁶ Uganda National Council for Science and Technology, (2002) Guidelines for Biosafety in Biotechnology for Uganda.

⁴⁶⁷ Draft National Biosafety Regulations, (2003), Document 38 Revised Draft Biosafety Regulations.

⁴⁶⁸ Jaffe (2006) *supra* note 53 at 17.

⁴⁶⁹ Wafula D and Clark N, 'Science and Governance of Modern Biotechnology in Sub-Saharan Africa- the Case for Uganda. (2005) 17 *Journal of International Development* 679-694 at 685.

was established under the UNCST Statute,⁴⁷⁰ is in charge of regulating genetic engineering and other biotechnologies.⁴⁷¹ The Draft National Biosafety Regulations (hereinafter Draft Biosafety Regulations) were passed under the patronage of the UNCST Statute. Commenting on the Draft Biosafety Regulations in 2004, Mayet stated that they appeared to be in their infancy.⁴⁷² Almost three years later, the Regulations still appear to be in draft form. The Draft Biosafety Regulations aim to ensure that in the use of GMOs, the environment including human health is protected.⁴⁷³

The Draft Biosafety Regulations define key terms such as ‘contained use’, ‘genetically modified organism’ and ‘modern Biotechnology’.⁴⁷⁴ They adopt the definition of these terms in the Protocol. The scope of the Draft Biosafety Regulations covers the ‘generation, import, export, contained use, release or placing on the market of any genetically modified organism or their ‘living products’.⁴⁷⁵ Pharmaceuticals and a range of other GMOs are excluded from the Regulations.⁴⁷⁶ Mayet rightly observes that the Regulations do not apply to GMO products (non-living).⁴⁷⁷

With respect to institutions, the Draft Biosafety Regulations establish three institutions, namely; the National Focal Point (NFP), the Competent Authority (CA) and the National Biosafety Committee (NBC).⁴⁷⁸ Provision is also made for the establishment of Institutional Biosafety Committees (IBCs).⁴⁷⁹ The Regulations name the Ministry of Lands, Water and Environment as the National Focal Point.⁴⁸⁰ The UNSCT is designated as the CA⁴⁸¹ and it is charged with the duty to establish a NBC that must be representative of the government, nongovernmental organizations as well as the private

⁴⁷⁰ No 1 of 1990.

⁴⁷¹ Mayet M, Comments on the Ugandan National Biosafety Framework September 2004 at 4, available at <http://biosafetyafrica.net/portal/DOCS/uganda-NBF.pdf>.

⁴⁷² Ibid.

⁴⁷³ Wafula, *supra* 469 at 690.

⁴⁷⁴ Regulation 1 (c), (e), and (f). Draft Biosafety Regulations.

⁴⁷⁵ Regulation 2 Draft Biosafety Regulations.

⁴⁷⁶ Regulation 2 (a), (b) and (c) Draft Biosafety Regulations.

⁴⁷⁷ Mayet, *supra* note 471.

⁴⁷⁸ Regulations 3 .1, 3.2, and 3.3 Draft Biosafety Regulations.

⁴⁷⁹ Regulation 3.4 Draft Biosafety Regulations.

⁴⁸⁰ Regulation 3.1 Draft Biosafety Regulations.

⁴⁸¹ Regulation 3.2 Draft Biosafety Regulations.

sector.⁴⁸² Persons interested in carrying out GMO related activities including contained use and release into the environment must seek approval.⁴⁸³

The Regulations make provision for public awareness and participation⁴⁸⁴ and the application of the precautionary principle when taking decisions.⁴⁸⁵ Provision is made for review of decisions, risk assessment and risk management.⁴⁸⁶ There is a requirement for clear labelling and identification and a confidentiality clause.⁴⁸⁷ A liability and redress regime, offences, and penalties are provided for.⁴⁸⁸

6.2.2 Uganda Biosafety Bill

The Uganda Biosafety Bill⁴⁸⁹ (hereinafter Biosafety Bill) was drafted in 2005 and published in October of the same year.⁴⁹⁰ The purpose of the Biosafety Bill include; establishing an institutional framework for regulation of GMO activities; establishing risk assessment and management standards; providing for public participation and access to information; and establishing a liability and redress regime.⁴⁹¹ The Draft Biosafety Regulations were enacted under the UNCST statute as earlier noted. Consequently, when the Biosafety Bill is enacted into law, these Regulations will not complement it. Rather, new Regulations will be enacted to facilitate the implementation of the Biosafety Bill (then the Uganda Biosafety Act).⁴⁹²

The Biosafety Bill has a broad scope of application, which encompasses; imports; exports; research; contained use; development; release or placing on the market of any GMO or product thereof, for use as pharmaceuticals, FFP.⁴⁹³ In part II, It establishes three

⁴⁸² Regulation 3.3 Draft Biosafety Regulations.

⁴⁸³ Regulation 4 Draft Biosafety Regulations.

⁴⁸⁴ Regulation 5 Draft Biosafety Regulations.

⁴⁸⁵ Regulation 6.6 Draft Biosafety Regulations.

⁴⁸⁶ Regulations 7, 8 and 9 Draft Biosafety Regulations.

⁴⁸⁷ Regulations 11 and 12 Draft Biosafety Regulations.

⁴⁸⁸ Regulations 14 and 15. Draft Biosafety Regulations.

⁴⁸⁹ Uganda Biosafety Bill 2005.

⁴⁹⁰ <http://www.africabiotech.com/news2/article.php?uid=115>.

⁴⁹¹ Long title and Section 4 of the Biosafety Bill.

⁴⁹² Section 34 of the Biosafety Bill.

⁴⁹³ Section 3 Biosafety Bill.

institutions namely; the NFP, the National Competent Authority (NCA); and the NBC⁴⁹⁴ and sets out their functions.⁴⁹⁵ The Biosafety Bill prescribes an application and approval procedure for authorization to undertake any activity under the Bill.⁴⁹⁶ The Biosafety Bill makes provision for public awareness, participation and access to information.⁴⁹⁷ There is provision for appeals and reviews of decisions.⁴⁹⁸ Exemptions and simplified approval procedure under which certain GMOs may be exempted from authorization and others subject to simplified information requirements are contained in the Bill.⁴⁹⁹ The Biosafety Bill makes provision for a confidentiality clause, and includes identification and labeling provisions.⁵⁰⁰ Finally, the Bill makes provision for; risk assessment and management;⁵⁰¹ a liability and redress regime;⁵⁰² unintentional release, inspection and enforcement;⁵⁰³ and offences and penalties.⁵⁰⁴ The Bill contains four Annexes, which provide for; information required in applications under section 14; additional information required in case of placing on the market; general principles and specific requirements for risk assessment and management; and the composition of the NBC.⁵⁰⁵

6.3 Relevant Policy

6.3.1 The National Biotechnology and Biosafety Policy

The National Biotechnology and Biosafety Policy (National Policy) contains the vision of the Ugandan Government for Uganda concerning biotechnology. The vision is ‘to make Uganda a country fully and safely utilizing biotechnology in national development’.⁵⁰⁶ The Government of Uganda undertakes to promote and facilitate safe development and

⁴⁹⁴ Sections 5.1, 6.1 and 8.1 respectively, Biosafety Bill.

⁴⁹⁵ Sections 5.1, 7 and 9 respectively, Biosafety Bill.

⁴⁹⁶ Section 14 Biosafety Bill.

⁴⁹⁷ Section 17 Biosafety Bill.

⁴⁹⁸ Section 20 Biosafety Bill.

⁴⁹⁹ Section part VI, sections 22 and 23 Biosafety Bill.

⁵⁰⁰ Part VI, sections 24-26 Biosafety Bill.

⁵⁰¹ Section 27 and 28 Biosafety Bill.

⁵⁰² Section 31 Biosafety Bill.

⁵⁰³ Section 29 and 30 Biosafety Bill.

⁵⁰⁴ Section 32 Biosafety Bill.

⁵⁰⁵ Annexes I, II, III and IV respectively.

⁵⁰⁶ Part 4.1.2 National Policy.

sustainable application of biotechnology.⁵⁰⁷ The Government of Uganda seeks to achieve the following under its National Policy: build and strengthen national capacity in biotechnology through research and development; promote the utilization of biotech living products and processes as tools for national development; and provide a regulatory and institutional framework for biotechnology development and applications. In addition, ensure public and environmental safety in biotechnology development and application; determine measures for risk assessment and management for all biotechnological applications; and provide for measures for biotechnology and biosafety monitoring and evaluation.⁵⁰⁸

The National Policy contains policy statements and action plans regarding every area identified in its objectives. Regarding legal and regulatory framework, the Government seeks to put in place requisite legal and regulatory regime that will balance promotional and safety aspects through the promulgation of a Biotechnology and Biosafety Act.⁵⁰⁹

6.3.2 The Guidelines for Biosafety in Biotechnology for Uganda

The National Biosafety Guidelines were drafted under section 3 (a) of the Uganda National Council for Science and Technology Statute No 1 of 1990. The objectives of the Guidelines include; ensuring public and environmental safety in research and development (R&D) and industrial applications; determining the measure for risk assessment and evaluation in GMO related activities; and promoting opportunities for the application and exploitation of biotechnology.⁵¹⁰ The Guidelines provide procedure for risk assessment and risk management measures;⁵¹¹ procedure for release and commercialization of rDNA organisms;⁵¹² and emergency procedures.⁵¹³

⁵⁰⁷ Part 4.1.1 National Policy.

⁵⁰⁸ Part 4.1.5 National Policy.

⁵⁰⁹ Part 4.4.1 and 4.4.2.6 National Policy.

⁵¹⁰ 1.1 National Biosafety Guidelines.

⁵¹¹ 3.0 National Biosafety Guidelines.

⁵¹² 3.8 National Biosafety Guidelines.

⁵¹³ 3.11 National Biosafety Guidelines.

CHAPTER 7

CRITIQUE OF UGANDA'S BIOSAFETY REGIME

7.1 Scope and Exclusions

The scope of the Draft Biosafety Regulations cover generation, import, export, contained use, release or placing on the market of GMOs or GMO living products as stated earlier.⁵¹⁴ Non-living products of GMOs, such as foodstuffs, are therefore excluded from the ambit of the Regulations. As pointed out earlier, non-living products of GMOs are equally potentially hazardous as their living counterparts and hence require regulation.⁵¹⁵ Therefore, this provision is rendered inadequate, as it would not effectively protect human being and the environment from potential harm likely to be caused by non-living GMO products.

Fortunately, however, the Biosafety Bill has a wider scope of application, which is all-inclusive.⁵¹⁶ Its scope extends to all activities mentioned under the Draft Biosafety Regulations⁵¹⁷ and to products of GMOs whether intended for; release into the environment, use as pharmaceuticals; or FFP. In addition, the Biosafety Bill applies to the development of GMOs.⁵¹⁸ Although the provision does not expressly mention the inclusion of non-living products of GMOs, the inclusion of pharmaceuticals which are clearly non-living products implies that these are included.

The Biosafety Bill's comprehensive coverage of GMOs is commendable. Such a provision is welcome as it adopts the approach that, in order to take precautionary measures, all GMOs, their products and related activities must be subject to regulation.⁵¹⁹ It is hoped therefore that when the Bill is enacted into law, it will afford the requisite safety required for the application of biotechnology in Uganda

⁵¹⁴ Regulation 2 Draft Biosafety Regulations.

⁵¹⁵ See chapter 3 part 3.3.1 of this paper. See also Mayet, *supra* note 241 at 2.

⁵¹⁶ Section 3 Biosafety Bill.

⁵¹⁷ These activities are; imports, exports, contained use, release or placing on the market. See Regulation 2.

⁵¹⁸ Section 3 Biosafety Bill.

⁵¹⁹ Mayet, *supra* note 193 at 2.

7.2 Institutional Arrangements

The Draft Biosafety Regulations contain ineffective provisions on institutional arrangement. The Draft Biosafety Regulations establish the NFC, CA and NBC as stated earlier.⁵²⁰ The NFC and the CA serve as the contact with the CBD, and supervise, and control the implementation of the Act, respectively.⁵²¹ The NBC is to be established by the CA and it is required to have representation from the government, NGOs and the private sector.⁵²² However, a major omission is that, duties and roles of the NBC are not prescribed. Consequently, it is not clear what role they play in the decision-making process.⁵²³ Where such roles are not outlined, it becomes difficult to determine whether there is transparency or not.

Further, the inclusion of the private sector in the NBC is questionable as members of this sector may include persons from the biotechnology industry.⁵²⁴ These persons cannot be in position to make impartial decisions, as they have interests in the promotion of the industry. The NBC is required to draw its own rules of procedure.⁵²⁵ This is not advisable as it is doubtful whether they would make rigorous rules of procedure particularly where the private sector may involve members from the biotechnology industry.⁵²⁶

The Biosafety Bill on the other hand, contains provisions with respect to institutions that are more effective. It establishes a number of institutions whose powers and roles are clearly prescribed. These as noted previously are the NFP, NCA and NBC.⁵²⁷ Two aspects are noteworthy regarding these institutions. First, numerous obligations are imposed on these bodies. They are not simply endowed with discretionary powers and functions such as considering applications and decision-making.⁵²⁸ One of the most important obligations is that imposed on the NCA to promote awareness, participation

⁵²⁰ Regulations 3.1, 3.2 and 3.3 Draft Biosafety Regulations.

⁵²¹ Regulation 3.1 and 3.3 Draft Biosafety Regulations.

⁵²² Regulation 3 Draft Biosafety Regulations.

⁵²³ Mayet, *supra* note 471 at 9.

⁵²⁴ *Ibid.*

⁵²⁵ Regulation 3 Draft Biosafety Regulations.

⁵²⁶ Mayet, *supra* note 471 at 9.

⁵²⁷ See Sections 5-9 Biosafety Bill.

⁵²⁸ For functions of institutions, see sections 5.1, 6.1, 7, and 9 of the Biosafety Bill. See also Rohlwink, *supra* note 352

and education on matters related to biosafety, including decision-making.⁵²⁹ Although the details of how this is to be achieved are not set out, it is submitted that this provision should contribute towards ensuring effective public participation.

Another element worth noting is the composition of the NBC, a body that will play an advisory role to the NCA.⁵³⁰ The NBC comprises of fifteen members who are representative of key stakeholders including; Government Agencies; the private sector; academic institutions; and civil society.⁵³¹ The NBC will therefore have a multidisciplinary representation, necessary when dealing with the complexities of GMOs.⁵³² These provisions are largely based on those set out in the African Model Law, which is very elaborate in this respect.⁵³³ The composition of the other institutions is unfortunately not prescribed.

Effective provisions on institutional arrangement are very important because, the institutions implement provisions of biosafety laws. As such, it is imperative that their powers and duties are well set out. This will arguably facilitate their efficiency and in turn promote adequate protection.

7.3 Application and Approval Procedures

Arguably, the Biosafety Bill contains precise provisions relating to applications and approval procedures. The Biosafety Bill states clearly that persons who wish to carry out a GMO or GMO product related activities require written authorization, obtainable following a written application.⁵³⁴ The Bill also specifies additional information which applicants are required to submit including comprehensive risk assessment, information on previous approvals and rejections.⁵³⁵ The Information included in applications appears to be comprehensive and should arguably provide decision-makers with sufficient detail

⁵²⁹ Section 7.6 Biosafety Bill.

⁵³⁰ Section 8 Biosafety Bill.

⁵³¹ Section 8.2, Biosafety Bill read with Annex IV.

⁵³² Mayet, *supra* note 241 at 22.

⁵³³ Article 3, Africa Model Law.

⁵³⁴ Section 14.1 and 14.2, Biosafety Bill.

⁵³⁵ Section 14.3 (a) and (c), Biosafety Bill.

to facilitate reasoned decision-making. The provisions of the Draft Biosafety Regulations governing applications and approval are worth noting as they state the type of information required from the applicant.⁵³⁶ However it is noted that the regulations only refer to an ‘assessment’ report.⁵³⁷ It does not specify whether it is a risk assessment or EIA which is required. It is submitted that such a provision is not workable. There is need for clarity in this respect such that applicants are fairly well informed about what is required of them during the application process.

7.4 Decision-making Procedure

A number of weaknesses are noted under the decision-making provisions of the Draft Biosafety Regulations and the Biosafety Bill. Under the Regulations, the CA is obliged to comply with the National Biosafety Guidelines when examining an application prior to an approval.⁵³⁸ While the Guidelines set out in some detail the risk assessment procedure to be followed, the decision-making procedure are regarded as problematic as the CA is the sole decision making body.⁵³⁹ Worse still, the composition of this body is unknown.⁵⁴⁰ The Regulations only state that the UNCST is designated as the CA but do not specify its composition.⁵⁴¹ The CA should preferably be assisted by an independent body such as the NBC in the decision-making process through giving advice.⁵⁴²

The Bill does not explicitly set down under its decision-making provisions what considerations must be taken into account in arriving at a decision.⁵⁴³ Neither does it state whether the opinion of the public obtained through the public participation process will be taken into consideration. However, as will be noted in other sections of the Bill, risk assessment, provision for public input and the precautionary principle are all provided for and these aid in the decision making process.⁵⁴⁴

⁵³⁶ Regulation 4.3 Draft Biosafety Regulations.

⁵³⁷ Regulation 4.3 (b) Draft Biosafety Regulations.

⁵³⁸ Regulation 6.1 Draft Biosafety Regulations.

⁵³⁹ Mayet, *supra* note 471 at 11.

⁵⁴⁰ *Ibid.*

⁵⁴¹ Regulation 3.2 Draft Biosafety Regulations.

⁵⁴² Mayet, *supra* note 471 at 12.

⁵⁴³ Section 15 Biosafety Bill.

⁵⁴⁴ See part 6.2.2 of this paper.

Notwithstanding the above stated, there are some good points worth noting concerning decision-making under the Draft Biosafety Regulation and the Biosafety Bill. The provisions of the Draft Regulations appear to be fairly well defined in the sense that they set out considerations based on which decisions will be made.⁵⁴⁵ These include; the precautionary principle; socio-economic impacts and risk assessments, which are all set out in separate sections.⁵⁴⁶ The Bill on the other hand, categorically stipulates under its risk assessments provisions that the NCA shall base its decisions on the precautionary principle, risk assessment and the advice of the NBC.⁵⁴⁷ Generally the provisions in question under both the Draft Regulations and the Biosafety Bill are submitted to be weak and inadequate.

7.5 Review of Decisions

Both the Regulations and the Biosafety Bill provide for the review of decisions.⁵⁴⁸ This power to review is essential because circumstances may change, and further risks to human health and the environment may become known over time.⁵⁴⁹ Therefore, if new information or a review of existing information point toward further risks to the environment, biological diversity or socio-economic conditions, an approval may be withdrawn or subjected to additional conditions.⁵⁵⁰ This is submitted to be one of the strengths of the biosafety regime.

7.6 Public Awareness and Participation

The Draft Biosafety Regulations contain inadequate and ineffective provisions on public participation. The Draft Biosafety Regulations appear to mix up several related issues such as access to information, public participation by way of comment, and

⁵⁴⁵ Regulation 6 Draft Biosafety Regulations.

⁵⁴⁶ Regulations 6.6, 6.7 and 8 respectively, Draft Biosafety Regulations.

⁵⁴⁷ Section 27.5, Biosafety Bill.

⁵⁴⁸ Regulation 7 Draft Biosafety Regulations and Section 21 Biosafety Bill.

⁵⁴⁹ Section 21.1 Biosafety Bill.

⁵⁵⁰ Regulations 7.1 and Section 21.1 Biosafety Bill.

consultation.⁵⁵¹ In addition, the public participation procedures are found to be inadequate in several respects. First, the Draft Regulations do not clearly specify the right to participate in the consultation process. Rather the discretion is given to the CA to determine when the public will be consulted.⁵⁵² Secondly, the period within which the public is expected to furnish their comments is not prescribed and the discretion appears to be left with the CA to decide.⁵⁵³ Notwithstanding any benefits associated with this approach, it is advisable that a standard period for comment is prescribed in the Regulations and the CA granted the discretion to extend the period under special cases. The need for clear provisions on public participation in environmental governance generally and in biosafety regulation in particular cannot be overstated.

The public participation provisions in the Biosafety Bill appear largely adequate. The Biosafety Bill guarantees the right of access to information,⁵⁵⁴ which is a very important tool, as this will enable the public to access relevant information. Public consultation is provided for, which guarantees the right to participate and the period for consultation is determined by the NCA on a discretionary basis.⁵⁵⁵ The discretion to determine the time needed for consultation is important because some applications will require more time than others will. In any case, it is guaranteed that enough time will be given for such process before a decision is made.

These public participation provisions are largely based on the African Model Law, which draws from Principle 10 of the Rio Declaration. Principle 10, distinctly states three pillars of public participation, namely the right to information, the right to participate in environmental decision-making and access to mechanism on redress and justice if their rights are violated.⁵⁵⁶

⁵⁵¹ Ibid at 10. See Regulation 5.

⁵⁵² Ibid.

⁵⁵³ Ibid.

⁵⁵⁴ Section 17.2 Biosafety Bill.

⁵⁵⁵ Section 17.3 Biosafety Bill.

⁵⁵⁶ Mayet, *supra* note 193 at 210.

7.7 Risk Assessment and Risk Management

The Draft Biosafety Regulation provides for risk assessment in terms that are rather ambiguous.⁵⁵⁷ A risk assessment is required before GMO related activities including importation, contained use, release or placing on the market can be authorized, and, the applicant or the CA may carry out this assessment ‘as appropriate’.⁵⁵⁸ The CA may require the applicant to bear the costs for evaluating the risk assessment or carrying out the risk assessment.⁵⁵⁹ Risk assessment must be done in accordance with the National Biosafety Guidelines.

These provisions are found to be inadequate for a number of reasons. First, there appears to be confusion between the risk assessment, which is the obligation of the applicant, and that, which is the responsibility of the CA.⁵⁶⁰ Preferably, the applicant must conduct a risk assessment, and where the need arises for verification, the CA may authorise another assessment and request the applicant to bear the costs. The Regulations state that the applicant or CA shall conduct risk assessment as appropriate, however, ‘as appropriate’ is subject to interpretation and there is no indication of who determines it or how it would be determined. Further, there is no indication of the scope of the risk to be investigated, that is whether it is risk to human and animal health, or the environment or both. The Regulations also make provision for exemption of risk assessment. The CA, where it is satisfied that the GMO will not cause any risk to the environment or human health may not require risk assessment.⁵⁶¹ It is very unlikely that a GMO can be considered not risky to the environment or human health to warrant such an approach.⁵⁶²

Although earlier, it was stated that the Draft Biosafety Regulations contains vague risk assessment provisions; these however, have certain merits. For instance, the fact that assessment is to be guided by the National Biosafety Guidelines. The Guidelines set out

⁵⁵⁷ Regulation 8.1-8.4 Draft Biosafety Regulations.

⁵⁵⁸ Regulation 8.2 and 8.3 Draft Biosafety Regulations.

⁵⁵⁹ Regulation 8.4 Draft Biosafety Regulations.

⁵⁶⁰ Mayet, *supra* note 471 at 13. See Regulation 8.1.

⁵⁶¹ Regulation 6.4 Draft Biosafety Regulations.

⁵⁶² Mayet, *supra* note 471 at 12.

detailed procedures for risk assessment and risk management, which should ensure uniformity and clarity.

The risk assessment provisions under the Biosafety Bill are arguably adequate. Risk assessments must be undertaken for all GMO related activities except as noted previously, in the unfortunate case when the NCA and NBC decide otherwise.⁵⁶³ The scope of the risk assessment is wide and it includes consideration of impact GMO related activity on human health, biological diversity, the environment, socio-economic conditions and cultural values.⁵⁶⁴ The Bill requires any persons with a stake in the process, or where their participation is likely to cause a conflict of interest, should not engage in evaluation of risk assessment.⁵⁶⁵ Where an independent risk assessment cannot be done or where the independence of a risk assessment cannot be verified, the NCA is empowered to reject the application.⁵⁶⁶

Although the Biosafety Bill contains arguably adequate risk assessment provisions, one major weakness is noted. The relevant section commences as follows; ‘Except as provided for in this Act or as the NCA in consultation with the NBC may decide, no GMO or product of GMO activity will take place without assessment of the impact and the risks posed...’⁵⁶⁷ Undertaking risk assessments therefore, appears to be discretionary in certain circumstances. Under the exemption procedure, the NCA and the NBC may exempt certain GMOs or their products from authorization.⁵⁶⁸ It is presumed that this is one of circumstances when the NCA and NBC would exercise their discretion to bypass risk assessment. It is submitted, however, that the idea of bypassing a risk assessment is not desirable given the uncertainty surrounding GMOs.

As far as risk management is concerned, the NCA is empowered to request any person responsible for any GMO related activity to take measures necessary to prevent and limit

⁵⁶³ Section 27.1 Biosafety Bill.

⁵⁶⁴ Ibid.

⁵⁶⁵ Section 27.7 Biosafety Bill.

⁵⁶⁶ Section 27.8 Biosafety Bill.

⁵⁶⁷ Section 27.1 of the Biosafety Bill.

⁵⁶⁸ Section 22.1 and 22.2 Biosafety Bill.

any damage to human or animal health, biological diversity or the environment.⁵⁶⁹ The responsible person may also have to restore the environment to its original state as far as it is feasible if requested to do so by the NCA.⁵⁷⁰ Moreover, the Bill enumerates the measures that the responsible persons should take. Notable among these is the duty to submit periodic reports with respect to the monitoring and evaluation of risks carried after the approval.⁵⁷¹

7.8 Confidentiality and Access to information

Both the Draft Biosafety Regulations and the Biosafety Bill contain provisions on confidentiality that restrict access to information. The Draft Biosafety Regulations make provision for the protection of confidential business information.⁵⁷² The CA determines what amounts to confidential information after an applicant makes a claim for confidentiality. Certain information is however, not afforded such protection and includes; the description of the GMO, methods and plans of monitoring, and the evaluation of foreseeable effects.⁵⁷³ The CA may trump the confidentiality clause and disclose confidential information pursuant to a court order or in the interest of the public.⁵⁷⁴

Regulation 12.2 of the Draft Biosafety Regulations specifically stating information that must be disclosed is based on Article 21.6 of the Biosafety Protocol. This is problematic as the Biosafety Protocol sets the minimum standard. Domestic regulation should not restrict the accessible information to the content of Article 21.6 of the Protocol.⁵⁷⁵ This is because, when the right of access to information by the public is restricted, it hinders any meaningful participation by the public.⁵⁷⁶ Additionally, it appears the CA is given a great deal discretion in determining what information should be protected.

⁵⁶⁹ Section 28.1 Biosafety Bill.

⁵⁷⁰ Ibid.

⁵⁷¹ Section 23.3 (f) Biosafety Bill.

⁵⁷² Regulation 12 Draft Biosafety Regulations.

⁵⁷³ Regulation 12.2 Draft Biosafety Regulations.

⁵⁷⁴ Regulation 12.3 Draft Biosafety Regulations.

⁵⁷⁵ Mayet, *supra* note 471 at 17.

⁵⁷⁶ Ibid at 16.

The Biosafety Bill provisions for confidentiality appear to follow the trend of the Draft Biosafety Regulations, which is rather restrictive.⁵⁷⁷ While the NCA in consultation with the applicant determine what information will be protected, only limited information as indicated in the Draft Biosafety Regulations is made accessible.⁵⁷⁸ This effectively means that a great deal of information will be kept away from interested parties such as members of the public.

These provisions are submitted to be ineffective and unworkable mainly because they restrict access to information. This inevitably adversely affects the public participation process, which as pointed out earlier is very vital in environmental protection.

7.9 Exemptions and Fast –Track Procedure

The Biosafety Bill provides for exemptions and a simplified approval Procedure.⁵⁷⁹ The NCA, in consultation with the NBC, is empowered to exempt certain GMOs from authorization.⁵⁸⁰ Further, the NCA must maintain a list of GMOs or products that are exempt from authorization. It is submitted that such provisions could defeat the purpose of biosafety regulation. In addition, such an approach is not precautionary, as it does not subject all GMOs or their products to risk assessment. It is unclear whether exempted GMOs will be subject to any form of risk or impact assessment.

The Biosafety Bill provides for simplified approval procedures to be applied by the NCA in consultation with the NBC where it determines that sufficient scientific knowledge is available for risk management.⁵⁸¹ It is submitted that, it is highly unlikely that sufficient information on a GMO can be obtained to warrant simplified procedures, there is simply too much uncertainty and such an approach could be extremely risky.⁵⁸²

⁵⁷⁷ Section 24.2 Biosafety Bill.

⁵⁷⁸ Ibid.

⁵⁷⁹ Sections 22 and 23 Biosafety Bill.

⁵⁸⁰ Section 22.1 Biosafety Bill.

⁵⁸¹ Section 23.1 Biosafety Bill.

⁵⁸² Mayet, *supra* note 471 at 12.

7.10 Unintentional Release and Emergency Measures

The Draft Biosafety Regulations and the Biosafety Bill make express provision for unintentional release and emergencies. These provisions are arguably adequate. The CA, under the Draft Biosafety Regulations, must ensure that the applicant has drawn up an emergency plan before any approval is made.⁵⁸³ Additionally, the CA must ensure that the applicant furnishes persons likely to be affected by any accidents with information on necessary safety measures.⁵⁸⁴ Under the Biosafety Bill, the NCA must develop, maintain and use an accident containment strategy to human health, biological diversity and the environment in case of accidents resulting from genetic engineering or use of GMOs or their products.⁵⁸⁵ If these provisions are implemented, containing emergencies resulting from GMO activity will arguably be made easier and hopefully less damage would be expected when these occur.

7.11 Liability and Redress Regime

The liability and redress provisions in the Biosafety Bill are arguably comprehensive and just.⁵⁸⁶ It attempts to capture all the essential relevant elements of a liability regime identified to include; standard of proof; nature of redress; and insurance and/or financial security.⁵⁸⁷ Notably, liability under the Bill extends to the supplier and developer in addition to the person responsible for the activity and the standard of liability provided for is strict.⁵⁸⁸ The extension of liability to suppliers and developers is undoubtedly just considering that these often have the financial capacity to compensate for damages caused. With regard to the strict standard of proof, this will generally motivate persons dealing with GAO's to be extremely precautionous

Also worth noting, is the fact the Bill grants legal standing to private persons, or group of persons, who want to seek redress for breach or threatened breach relating to the

⁵⁸³ Regulation 10 (a) Draft Biosafety Regulations.

⁵⁸⁴ Regulation 10 (b) Draft Biosafety Regulations.

⁵⁸⁵ Section 28.4 Biosafety Bill.

⁵⁸⁶ Section 31 Biosafety Bill.

⁵⁸⁷ Feris, *supra* note 227 at 12/26.

⁵⁸⁸ Section 31.2 and 1 Biosafety Bill.

environment, biological diversity, human health or socio-economic conditions.⁵⁸⁹ Where these persons do not succeed in an action brought in public interest, they are exonerated from paying costs.⁵⁹⁰ This should encourage public interest litigation relating to biosafety regulation and environmental protection.

7.12 Labelling and Identification

The labeling and identification provisions contained in the Biosafety Bill appear to be satisfactory. A comprehensive labelling and identification/traceability system is one of key features of a biosafety law.⁵⁹¹ The Bill provides that GMOs and their products must be clearly identified and labeled as GMOs.⁵⁹² This identification should include relevant traits and characteristics given with sufficient detail to enable traceability and facilitate verification.⁵⁹³ The threshold for a consignment to be considered a GMO is set at 1.0%.⁵⁹⁴ This threshold is relatively low and will ensure that consignments with the slightest trait of GMOs are labelled, hence protecting consumers health and choice. In addition, a GMO, products of GMOs or consignment of GMOs or products of GMOs must state any known allergies, reactions or side effects.⁵⁹⁵ This will clearly provide users with relevant information hence rendering better protection. The Bill requires exporters to segregate GMOs or GMO related products from non-GMO products during their handling and transportation which is very important in order to prevent contamination.⁵⁹⁶ These provisions generally appear to be workable.

7.13 Offences and Penalties

In the implementation and enforcement of environmental law, criminal sanctions are noted as one of the key tools.⁵⁹⁷ The Ugandan regulatory system sets out a rather comprehensive section on offences and penalties. What is remarkable is the wide range of

⁵⁸⁹ Section 31.7 Biosafety Bill.

⁵⁹⁰ Section 31.8 Biosafety Bill.

⁵⁹¹ Mayet, *supra* note 193 at 11.

⁵⁹² Section 26.2 Biosafety Bill.

⁵⁹³ *Ibid.*

⁵⁹⁴ Section 26.2 Biosafety Bill.

⁵⁹⁵ Section 26.3 Biosafety Bill.

⁵⁹⁶ Section 25 Biosafety Bill.

⁵⁹⁷ Glazewski, *supra* note 72 at 118.

acts that are criminalised and the severe nature of penalties prescribed under the Biosafety Bill.⁵⁹⁸ A person convicted of an offence under the Biosafety Bill will be liable to a fine or imprisonment of not less than five years but not exceeding ten years or both. It is submitted that harsh sentences are necessary, as this will motivate persons dealing with GMOs to take extra caution in ensuring compliance with the law. This should subsequently ensure greater safety and protection of human, animal, and plant health and the environment.

Acts that are regarded as offences include: importing GMOs or their products without permission; violating conditions attached to an approval; failure to label and package GMOs or their products in accordance to the law; and using labeling and packaging that is false, misleading or deceptive.⁵⁹⁹ These above provisions are commendable in this respect but it is hoped that they will not be undermined by resource constraints when it comes to compliance and enforcement

7.14 Compliance and Enforcement

The Biosafety Bill contains satisfactory provisions on compliance and enforcement. The NCA is charged with the duty of designating inspectors.⁶⁰⁰ Although the details of their qualifications are not set out, it is assumed that they will be trained to carry out their duties. An inspector will bear a certificate, which will distinguish them from possible impostors. The powers given to the inspectors are very broad and include the power to enter onto premises, seize items and to issue directives.⁶⁰¹ While these provisions are praiseworthy, unless Uganda allocates resources and capacity towards compliance and enforcement, which are currently constrained, these provisions may be undermined.

⁵⁹⁸ Section 32 Biosafety Bill.

⁵⁹⁹ Section 32.1(a), (b), (e) and (g). Biosafety Bill.

⁶⁰⁰ Section 30.1 Biosafety Bill.

⁶⁰¹ Section 30.4 Biosafety Bill.

7.15 Legal Authority

It appears that biosafety regulation in Uganda does not have adequate legal authority. The Biosafety Bill has not yet been enacted into law. The Draft Biosafety Regulations were promulgated under the UNCST Statute and a review of its provisions indicates that it does not provide for the promulgation of regulations.⁶⁰² As such, the UNCST statute does not support the regulations. The Draft Biosafety Regulations may therefore, arguably be invalid.

7.16 Conclusion

As noted above the regulatory framework in Uganda is still rather ad hoc in nature and is still under development. It appears nonetheless that efforts are being made to address pertinent biosafety issues in an adequate manner. The Draft Biosafety Regulations, notwithstanding its lack of legal authority, has some good points that are worth noting. The Draft Biosafety Regulations attempt to address crucial issues in biosafety regulation. Notable among these are liability and redress, the precautionary principle, public participation and labeling and identification. One of its strongest points is arguably the extension of liability to developers and suppliers of GMOs in addition to the users. This clearly goes ahead of the Biosafety Protocol, which does not contain liability and redress provisions. Weaknesses noted under the Regulations include the fact that, their scope of application is restricted to living products, and the fact that the risk assessment provisions are ambiguous and unclear. Another serious weakness with the Draft Regulations is that, they appear not to have any legal force as such its application is arguably not mandatory.

The Biosafety Bill, which represents Uganda's future biosafety law on the other hand, is largely adequate. The Biosafety Bill similarly addresses the crucial biosafety issues and it does this in a more adequate manner than the Draft Biosafety Regulations. Its strengths include a comprehensive liability and redress regime and clear labeling and identification provisions. Since Uganda has shown interest in enacting a legally binding piece of legislation for biosafety, it is submitted that the Draft Regulations should be disregarded and more efforts be directed towards passing the current Biosafety Bill into law. The

⁶⁰² Wafuula 2005 in Jaffe (2006), supra note 53 at 26.

subsequent chapter therefore will attempt to suggest some ideas on how to improve the proposed Bill.

CHAPTER 8

COMPARATIVE ANALYSIS OF SOUTH AFRICA AND UGANDA'S BIOSAFETY REGIMES

8.1 Introduction

This chapter seeks to conduct a comparative analysis of the South African regulatory regime and Uganda's future biosafety regulatory regime (the Biosafety Bill). The objective is to determine how the two countries deal with specified issues in their biosafety regulatory systems. Therefore, differences and similarities in the systems of the two countries will be highlighted. This chapter will also test to what extent the two countries have attempted to comply with international obligations with respect to biosafety especially the Biosafety Protocol and the African Model Law. Where shortfall and deficiencies are noted, this paper will attempt to point out how these shortfalls may be remedied. The assessment will be done under the following themes utilised in the foregoing critical analysis of the two domestic regimes, namely: institutions; decision-making; public participation; risk assessment; liability and redress; labeling and identification; and Compliance and Enforcement.

8.2 Institutional Arrangement

The GMO Act establishes three institutions; these are the Executive Council, the Registrar and the Advisory Committee.⁶⁰³ The Ugandan Biosafety Bill⁶⁰⁴ provides for the establishment of three related institutions namely the NFP, the NCA and the NBCs. As far their duties are concerned, the Executive Council under the GMO Act and the concomitant, NCA under the Ugandan Bill, are charged with similar functions. The most significant function is decision-making concerning GMO related activities in their respective countries.⁶⁰⁵ While the GMO Act sets out the composition of the Executive Council,⁶⁰⁶ the Biosafety Bill specifically names the UNCST the NCA.⁶⁰⁷ It does not however stipulate the composition of this body. It is assumed that this body will most

⁶⁰³ Sections 3, 8 and 10 GMO Act respectively.

⁶⁰⁴ Sections 5, 6, and 8 respectively of the Biosafety Bill.

⁶⁰⁵ Section 4, GMO Act and Section 7 Biosafety Bill.

⁶⁰⁶ Section 3 GMO Act.

⁶⁰⁷ Section 6 .2 Biosafety Bill.

likely be composed of scientists considering that it is the National Council for Science. The NBC plays an advisory role to the NCA.⁶⁰⁸ It is parallel to the Advisory Committee under the GMO Act, which advises the Minister, the Council, and plays the role of the national advisory body.⁶⁰⁹

A noteworthy difference in the systems of the two countries is in the composition of the Advisory bodies, that is the NBC (Uganda) and the Advisory Committee (South Africa). While the Biosafety Bill provides for the representation of the civil society, which is crucial in decision-making regarding GMO, the GMO Act does not. The GMO Amendment Bill does not redress the situation. Another difference worth mentioning is that while the GMO Act establishes the office of the Registrar, the Ugandan system does not.

A similarity is noted in the extent of discretion awarded to the decision-making bodies. The Executive Council has the discretion, for instance, to determine when an EIA should be supplied by an applicant.⁶¹⁰ The trend appears to be the same in Uganda where the discretion to exclude risk assessment lies in the hands of the NCA in consultation with the NBC.⁶¹¹

Whereas the Biosafety Protocol requires each party to designate a NFP and NCA,⁶¹² the African Model law, which provides for the establishment of the foregoing institutions, goes further. It also provides for the establishment of the NBC and the IBC.⁶¹³ The institutional arrangements in the Ugandan system appear to be based on the African Model law and appear preferable to that based in South Africa as it provides for a multi disciplinary representation in decision-making.⁶¹⁴ Both countries need to consider reducing the discretion afforded to their key decision-making bodies in the context of biosafety regulation. Biosafety requires very stringent regulation and affording decision-

⁶⁰⁸ Section 9 Biosafety Bill, Ibid.

⁶⁰⁹ Section 11 GMO Act.

⁶¹⁰ Section 4 of the GMO Amendment Bill, which amends section 5 of the GMO Act.

⁶¹¹ Section 27.1 Biosafety Bill.

⁶¹² Article 19 Biosafety Protocol.

⁶¹³ Article 3 African Model Law.

⁶¹⁴ The Composition of the National Biosafety Committee, Article 3.3 African Model Law.

makers with too much discretion might render regulation defunct. Alternatively, there is need to ensure comprehensive representation of all relevant stakeholders on decision-making bodies and comprehensive public participation procedures.

8.3 Decision-making

A number of issues are central to ensuring effective decision-making. These include: risk assessment; the precautionary principle; socio-economic considerations; and public input.⁶¹⁵ While the Ugandan Biosafety Bill contains a decision-making procedure,⁶¹⁶ The South African regime does not. The Ugandan provisions are unfortunately, rather vague and imprecise, as earlier noted. They do not expressly indicate what considerations should to be taken into account in decision-making.⁶¹⁷ However, since the Biosafety Bill makes provision for the said considerations in separate sections as noted before, it would be safe to conclude that biosafety decisions should be ‘precautionary’ and ‘risk-based’ when the Bill takes effect. Regarding the South African system, it is safe to conclude from the circumstances that the above critical issues do not play any role in the decision-making process. This view is plausible because the GMO Act, its Regulations and the Amendment Bill do not provide for mandatory risk assessment, public participation or the application of the precautionary principle as noted earlier.

While the Ugandan system largely complies with the international law in this regard, the same is not true for South Africa. It is suggested that Uganda considers inserting a more precise provision in its Biosafety Bill, which clearly spells out the considerations to be taken into account in decision-making. Secondly, the Biosafety Bill should bind decision-makers to observe detailed procedure on decision-making to be contained in the Guidelines.⁶¹⁸ In the case of South Africa, a section on decision-making should be included in the GMO Amendment Bill in which all the important issues mentioned above are included. Although South Africa has, Guidelines (General) and (Advisory

⁶¹⁵ Biosafety Guide, *supra* note 39 at 79-81.

⁶¹⁶ Section 15 Biosafety Bill.

⁶¹⁷ See specifically section 15 of the Biosafety Bill.

⁶¹⁸ Section 34 of the Biosafety Bill makes provision for the enactment of Regulations and Guidelines. The Guidelines will give guidance on a wide range of issues including issue of permits. See section 34.3 (h).

Committee), for decision-makers, these so not include the important considerations under discussion. Due to their importance, these considerations should preferably be included in an Act, which has legal force as opposed to Guidelines, which may not be legally binding.

8.4 Public participation

The countries approaches to public participation are very different. While the Ugandan regime contains provisions on public participation that are largely adequate, the GMO Act does not contain any provisions on public participation. An adequate public participation regime should guarantee the right of citizens to information, the right to participate in decision-making and access to mechanisms of justice and redress when their rights are violated as noted previously. The Ugandan Biosafety Bill attempts to capture all these requirements and appears to be based on the African Model law, which is commendable. The South African situation, on the other hand, requires reform as public participation is a very important element in environmental decision-making. Much as access to information is guaranteed elsewhere in South Africa's Constitutional and framework environmental law,⁶¹⁹ its inclusion under the GMO legislation is imperative and makes its application much easier and accessible. Consequently, South Africa fails to comply with international law in this respect. South Africa should therefore consider making amendments to the GMO Act to include specific provisions on public participation.

8.5 Risk Assessment

In Uganda, no GMO or product of GMO activity may take place without assessment of risks except as otherwise provided for.⁶²⁰ This requirement appears to be discretionary. In instances where risk assessment is not conducted, it is not clear whether the authorities would be able to make informed decisions.⁶²¹ The trend appears to be the same in the South African regime where risk assessment is provided for only in the GMO Regulations as previously noted. The insertion of such a requirement in the Regulations

⁶¹⁹The Constitution section 32, section 31, NEMA and PAIA.

⁶²⁰ See section 27.1 Biosafety Bill.

⁶²¹ Biosafety Guide, supra note 39 at 217.

arguably renders its application discretionary. Such a requirement should preferably have been placed in the GMO Act.

Both Uganda and South Africa appear to be failing to meet their international obligation under the Biosafety Protocol in this respect. Uganda needs to redraft the provisions of its Bill relating to risk assessment and set the requirement as mandatory. It is proposed that South Africa adopts clear and precise provisions on risk assessment and these should be included in the GMO Act, through its amendment. The provisions in the African Model law are recommended as they provide for rigorous risk assessment.

8.6 Liability and redress

There are considerable differences in the way the biosafety regimes in Uganda and South Africa deal with liability and redress. While the Ugandan regime attempts to provide a comprehensive regime, the opposite is true for South Africa. As earlier noted, the crucial issues in a liability regime include: the type of loss that is remediable; the standard of care; time limits for bringing action; the person responsible for damage; and financial guarantees to compensate for damages. The Biosafety Bill, largely based on the Africa Model Law, attempts to cover all these issues, and appears to provide satisfactory regime.

On the contrary, South African law does not provide a comprehensive liability regime for GMOs. It contains a regime, which is said to be unjust as it makes the end users liable for damage.⁶²² The duty of care and emergency incidents provisions under South Africa's NEMA appear to remedy the situation. However, these are not comprehensive enough and may not be easily accessible. It is suggested that more comprehensive regime is included in the GMO Amendment Bill, which should make among others the supplier/developer of GMOs liable in case of damage; set the standard of proof as strict liability; provide for a wide scope of damage that is remediable; and make provision for financial guarantees to compensate for damages. Suppliers and developers are clearly better placed to remedy any damage financially and in terms of technical expertise. A strict liability will motivate concerned parties to be more diligent when using GMOs.

⁶²² Eastwood *supra* note 255.

Although the Cartagena Protocol does not set out a liability regime, the African Model Law does provide a comprehensive regime for liability and redress which African countries are encouraged to adopt in the absence of an adequate regime elsewhere under international law. South Africa should therefore seek guidance from the provisions of the African Model Law.

8.7 Labelling and Identification

The South African biosafety law does not provide for mandatory labeling of GMOs or GMO products. Conversely, in Uganda there is a requirement for clear labelling and identification in the proposed Bill. The Biosafety Protocol does not contain satisfactory provisions on labeling and identification as noted previously. Its provisions are rather ambiguous in this respect. The African Model Law however attempts to set out distinct requirements for labelling of GMOs on which the Ugandan Biosafety Bill relies. It is suggested that South Africa includes mandatory labelling provisions in its biosafety regulation through the amendment of the GMO Act. The provisions in the African Model Law are suggested as a template as they are clear and precise.

8.8 Compliance and Enforcement

In both countries, there is provision for enforcement of the biosafety regulations through offences and penalties as well as enforcement powers granted to inspectors. The Biosafety Bill of Uganda appears to have adopted the offence and penalty provisions under the African Model Law. There is a wider range of acts that are illegal there under including using false and deceptive labels. On the contrary, the offences under the GMO Act are very limited.⁶²³ There is a need therefore to include more offences under the offence provision. For instance, importing, releasing or placing on the market of any GMO or product of GMO without written approval should be criminalized. This would restrain persons from engaging in such activities without authorization, as they would be liable to punishment as opposed to if these acts are not criminalized.

⁶²³ Section 21 GMO Act.

As far as the penalties are concerned, the Ugandan Biosafety Bill stipulates harsh penalties for persons convicted under the proposed Act. It prescribes imprisonment for not less than five years and not exceeding ten years.⁶²⁴ The GMO Act provides for very moderate sentences such as imprisonment not exceeding two years. South Africa must consider including more severe penalties such as imprisonment for not less than five years and a fine. This is important because GMO related activities might have dire consequences hence warranting strict regulation.

The GMO Act and the Biosafety Bill both provide for inspectors who are charged with duties including investigating whether conditions of approval and provisions of the relevant laws are being implemented. In both systems, they are granted reasonable powers to enter premises with or without notice. They have powers to search, inspect and take samples. The Ugandan Bill however grants more powers that are relevant to the inspectors including the power to seize and the power to issue a directive. The power to seize and the power to issue directives are very important especially if the circumstances call for it.

8.9 Conclusion

There are a few noted similarities in the biosafety regulation in the two countries for instance regarding institutions and enforcement. Yet there are varied differences in their approach to more critical issues such as liability, public participation, labelling and risk assessment. From an overall perspective, Uganda's future biosafety framework appears to provide a more comprehensive and effective framework for biosafety regulation.

⁶²⁴ See section 32 Biosafety Bill.

CHAPTER 9

CONCLUSION

This study sought to conduct a critical and comparative analysis of biosafety regulation in South Africa and Uganda. The key question that the paper addressed was: which country's biosafety regime provides a more adequate regulatory framework? In the first instance, this paper considered international instruments relevant to biosafety regulation. These are the Cartagena Protocol on Biosafety and the non-binding African Model Law. It was noted that the negotiations of the Cartagena Protocol were highly controversial such that the final text of the Protocol reflects a compromise. Consequently, the Biosafety Protocol establishes only minimum standards in relation to biosafety. However, the Protocol does not inhibit states from exercising their rights under the state sovereignty doctrine which enables states to 'take action that is more protective' of their environments and thereby make legislation that fits into their local circumstances.⁶²⁵ Failure to provide a liability and redress regime is one of the outstanding weaknesses of the Protocol. However, plans are underway following the Kuala Lumpur COPs meeting to have a comprehensive liability regime enacted in compliance with the Protocol.⁶²⁶

It was also noted that the African Model Law contains comprehensive and arguably adequate provisions on biosafety regulation. The African Model Law makes use of the state sovereignty doctrine embraced by the Protocol to establish a more stringent biosafety regime. For instance, the African Model Law establishes a comprehensive and relevant liability and redress regime. However, its non-binding nature makes it imperative that member states must not only pledge but also implement it in their evolving biosafety legislation, if the Model Law is to serve any meaningful purpose. On this basis, this study found that South Africa's attempt to comply with the African Model Law is far below any expectations compared to Uganda.

⁶²⁵ Article 2.2 of the Biosafety Protocol.

⁶²⁶ Falkner and Gupta, *supra* note 38 at 18., also Article 27 protocol

In the domestic sphere, assessment of the South African biosafety regime indicated that the system is grossly inadequate. The GMO Act focuses on institutional arrangements and does not address core issues in biosafety. It lacks a liability and redress regime; contains discretionary requirements for risk assessment; makes inadequate provision for public participation and, does not provide for proper application of the precautionary principle. Although the GMO Amendment Bill seeks to make the GMO Act compliant with the Biosafety Protocol, it has invariably failed to improve the current regime. The said Bill is inadequate as it does not address key issues such as the liability and redress regime, the precautionary principle and public participation. As a consequence, the GMO Amendment Bill fails to cure the inherent weaknesses of the GMO Act thereby rendering the biosafety regime in South Africa neither relevant nor credible.

In Uganda, it was noted that current regulation is rather *ad hoc*. The Draft Biosafety Regulations and the Biosafety Bill were the key legislations reviewed. Concerning the Draft Biosafety Regulations, it was noted that these do not have any legal force. The UNCST statute does not contain provisions enabling the promulgation of such Regulations. Thus, application of these regulations is largely voluntary. The Ugandan Bill appears promising yet it is still aspirational. Some potential was noted in the Bill that is worth applauding. It is largely founded on the African Model Law to the extent that it provides for stringent regulation in critical tenets of biosafety. The controversial precautionary principle is adopted in the Bill as well as precise labeling and identification provisions. The Bill also takes cognizance of socio-economic considerations and issues of public participation in biosafety. While the Ugandan regime addresses the above and other contentious issues, the same cannot be said for South Africa. About a decade since the enactment of GMO Act together with the recent GMO Amendment Bill, South African biosafety regulation remains largely inadequate.

Differences and similarities were noted following the thematic comparative analysis of biosafety regulation in South Africa and Uganda. From an overall perspective, it was noted that, Uganda is more compliant with international law regulating biosafety than South Africa. Specifically, the Ugandan Biosafety Bill relies on the provisions of the

African Model Law. This position is admirable and it is hoped that other African countries developing Biosafety laws can follow Uganda's example. Major variances were noted in the way South Africa and Uganda deal with issues such as, liability and redress, the precautionary principle and labeling and identification. Similarities were noted in their approach to institutional arrangements and enforcement.

A key role that governments have to play is to protect the environment and its people from the potential harm caused by GMOs. It is imperative that, high standards of regulation of modern biotechnology are set since, the dangers associated with GMOs are not entirely known. Consequently, there is a likelihood of conflict as stringent regulation may impede GMO related activities in countries African countries that promote biotechnology. Inevitably, a compromise is needed in order to establish and maintain a balance of these competing interests. One way of achieving this compromise would be by ensuring maximum transparency through the active participation of the public in issues of biosafety.

BIBLIOGRAPHY

Books

Birnie P and Boyle A, *International Law and the Environment*, 2nd Ed, Oxford University Press 2002

Glazewski J, *Environmental Law in South Africa*, 2nd Ed, LexisNexis Butterworths Durban 2005

Kiss A and Shelton D, *International Environmental Law* 3rd Ed Transnational Publishers New York 2004

Sands P, *Principles of International Environmental Law* 2nd Ed Cambridge University Press 2003

Journal Articles:

Adler J, 'The Cartagena Protocol and Biological Diversity: Biosafe or Bio-sorry?' (1999-2000) 12 *Georgetown International Environmental Law Review* 761

Adler J, 'More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol' (2000) 35 *Texas International Law Journal* 173

Barron N, 'Throwing Caution to the Wind: A Critical Analysis of the EIA Provisions contained in the Genetically Modified Organisms Act of South Africa (2003) 10 *South African Journal of Environmental Law and Policy* 93

Burgiel S 'The Cartagena Protocol on Biosafety: Taking Steps from Negotiations to Implementation' (2002) 11 (1) *RECEIL* 53

Boutillon S, 'The Precautionary Principle: Development of an International Standard' (2001-2002) 23 *Michigan Journal of International Law* 429

Compton M ‘Applying World Trade Organization Rules to the Labelling of Genetically Modified Foods’ (2003) 15 *Pace International Law Review* 359

Cullet P ‘Liability and Redress for Modern Biotechnology’ (2006) 15 *Yearbook of International Environmental Law* 165-195

David M and Gavin G, ‘Genetically Modified Food Labeling and the WTO Agreements’ (2004) 13 (3) *RECEIL* 306

Dommelen, A. van (2000), ‘The Precautionary Principle: Dealing with controversy.’ *Biotechnology and Development Monitor*, No. 43, p. 8-11

Duall E, ‘A Liability and Redress Regime for Genetically Modified Organisms under the Cartagena Protocol’ (2004) 36 (1) *George Washington International Law Review* 173

Feris L, ‘Risk Management and Liability for Environmental Harm Caused by GMOs – The South African Regulatory Framework.’ 2006 *Potchefstroom Electronic Law Journal* 1-26

Gupta A, ‘Advanced Informed Agreements: A shared Basis for Governing Trade in Genetically Modified Organisms?’ (2001-2002) *Indiana Journals of Global Legal Studies*. 265

Heavin D, ‘The Biosafety Protocol and the SPS Agreement: Conflicts and Dispute Resolution’ (2003) 12 *Journal of Environmental Law and Practice* 373

Hill R et al, ‘Risk Assessment and Precaution in the Biosafety Protocol’ (2004) 13 (3) *RECEIL* 263

Kameri Mbote P, ‘Development of Biosafety Regulations in Africa in the Context of the Cartagena Protocol: Legal and Administrative Issues’ (2002) 11 (1) *RECEIL* 62

Mayet M, 'Why Africa should adopt the African Model Law on Biosafety in Biotechnology' (2004) 11 (2) *SAJELP* 195

McGinn K A, Symposium Articles and Note (1999-2000) 12 *Georgetown International Environmental Law Review* 695

Meijer E and Stewart R, 'The GM Cold War: How Developing Countries Can Go from Being Dominos to Being Players' (2004) 13 3 *RECEIL* 250

Nelkin D et al, 'The International Challenge of Genetically Modified Organisms Regulation' (1999-2000) 8 *New York University Environmental Law Journal* 523

Newell P and Mackenzie R, 'The 2000 Cartagena Protocol on Biosafety: Legal and Political Dimensions' (2002) 10 *Global Environmental Change*

Notes and Comments 'Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements. (2002) 96 *American Journal of International Law* 606

Saigo H, 'Agricultural Biotechnology and the Negotiation of the Biosafety Protocol' (1999-2000) 12 *Georgetown International Environmental Law Review* 779

Sand H.P, 'Labelling Genetically Modified Food: The Right to Know' (2006) 15 (2) *RECEIL* 185

Teel J, 'Regulating Genetically Modified Products and Processes: An Overview of the Approaches' (1999-2000) 8 *New York University Environmental Law Journal* 649

Wafula D and Clark N, 'Science and Governance of Modern Biotechnology in Sub-Saharan Africa- the Case for Uganda. (2005) 17 *Journal of International Development* 679-694

Wallis E, 'Fish Genes into Tomatoes: How the World Regulates Genetically Modified Organisms' (2004) 80 *North Dakota Law Review* 422

Other References:

Eastwood J, 'GMO Amendment Bill- Perpetuating the Shortcomings of the GMO Act.' Unpublished Paper presented at Environmental Law Association Workshop held in Cape Town on 24 February 2006

Falkner R and Gupta A, Implementing the Biosafety Protocol: Key Challenges, Chatham House Briefing Paper No. 4 (London: RIIA, 2004)

Fransen L, La Vina A, Dayrit F, Gatlabayan L, Santosa D.A and Adiwibowo S, 'Integrating Socio-Economic Considerations in Biosafety Decision Making: the Role of Public Participation.' WRI White Paper, 41

Governing Biotechnology in Africa: Towards Consensus on Key Issues in Biosafety, A 'living paper' prepared for the second session of the African Policy Dialogues on Biotechnology – Southern Africa, Harare Zimbabwe 20-24th September 2004

Jaffe G (2006) 'A Comparative Analysis of the National Biosafety Regulatory Systems in East Africa'. EPT Discussion Paper 146

Mayet M, 'Why we need to label GMO food' February 2006

Available at http://www.biosafetyafrica.net/_DOCS/ACB_GEFoodlabellingFactsheet.pdf

Mayet M, 'Critical Analysis of South Africa's Labelling Regulations for Genetically Modified Food, Feed and Products Derived from GM-FED Animals.' October 2004 Unpublished Paper

Available at <http://www.biosafetyafrica.net/portal/DOCS/SAGMLabellingAnalysis.pdf>

Mayet M, 'Comments on the Ugandan National Biosafety Framework' Unpublished Paper September 2004

Available at http://biosafetyafrica.net/portal/Docs/Uganda_NBF.pdf

Mayet M, 'Analysis of South Africa's GMO Act of 1997' Unpublished Paper, written for Biowatch South Africa, Spring 2000

Available at http://www.biosafetyafrica.net/portal/DOCS/SA_GMO_Leg_short.pdf

Mayet M, 'Comments on the Genetically Modified Organisms Amendment Bill (revised version), 2005 Unpublished Paper Available at

http://www.biosafetyafrica.net/portal/DOCS/ACB_comments_GMO_amend_bill.pdf

Mayet M, 'Critical Analysis of Pertinent Legislation Regulating Genetic Modification in Food and Agriculture in South Africa Unpublished Paper May 2001 Available at

http://www.biosafetyafrica.net/portal/DOCS/SA_GMO_Leg_long.pdf

Mackenzie R, 'International Regulation of Modern Biotechnology' A paper written for Foundation for International Environmental Law and Development. (FIELD)

Available at <http://www.ids.ac.uk/ids/KNOTS/PDFS/RMwp.pdf>

Newell P, (1997) 'Biotechnology and the Politics of Regulation' IDS Working Paper 146 January 2002

Rohlwink I, 'A Critical Analysis of the Genetically Modified Organisms Bill: Does it remedy the Inadequacies of the Current Regime?' (2006) Unpublished LLB Dissertation, University of Cape Town, Cape Town.

International Instruments:

African Model Law on safety in Biotechnology

Available at <http://saqa.org.za/ncf/docs/modellaw.html>

Cartagena Protocol on Biosafety 39 ILM 1027 (2002)

Convention on Biological Diversity 31 ILM 818 (1992)

South African Legislation:

Constitution of the Republic of South Africa Act (108 of 1996)

Foodstuffs, Cosmetics and Disinfectants Act (54 of 1971)

Genetically Modified Organisms Act (15 of 1997)

Genetically Modified Organisms Amendment Bill (GG 27913 dated 26 August 2005)

National Environmental Management Act (107 of 1998)

Promotion of Administrative Justice Act (3 of 2000)

Promotion of Access to Justice Act (2 of 2000)

South African Cases:

Biowatch Trust V the Registrar Genetic Resources and Others 2005 (4) 111 T.

Hichange Investments (Pty) Ltd v Cape Produce Company (Pty) Ltd t/a Pelts Products and Others 2004 (2) SA 393 (ECD).

South African Subsidiary legislation:

Draft Biosafety Policy (GN 1576/2005 in GG 27193 dated 26 August 2005)

List of Activities and Competent Authorities Identified In terms of Sections 24 and 24D of the National Environmental Management Act 1998 (GNR 386/2006 in GG 28753 dated 21 April 2006)

Regulations under the GMO Act (G.N.R 1420 dated 26 November 1999)

Regulations relating to the Labelling of Foodstuffs obtained through certain Techniques of Genetic Modification (GNR 25 GG 25908 dated 16 January 2004)

Regulations on Fair Administrative Procedures Promulgated (GN R1022 in GG 23674 dated 31 July 2002)

Guideline Document for Use by the Advisory Committee when considering Proposals/Applications for Activities with Genetically Modified Organisms (GN 1047/2004 in GG 26422 dated 11 June 2004)

Guideline Document for Work with Genetically Modified Organisms (GN 1046/2004 in GG 26422 dated 11 June 2004)

Ugandan Legislation:

Draft National Biosafety Regulations 2004

Uganda Biosafety Bill 2005

Other Documents:

Guidelines for Biosafety in Biotechnology for Uganda, 2002

National Biotechnology and Biosafety Policy, 2003

Internet Sites:

<http://www.biodiv.org>

<http://bch.biodiv.org/>

<http://www.biosafetyafrica.net/>

<http://www.biowatch.org.za/main.asp?include=links.htm>

<http://www.biodiv.org/biosafety/default.aspx>

